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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-01

TITLE: Conduct of a Needs Assessment for EPA's Integrated Risk Information System (IRIS) Program

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents)

PERIOD OF PERFORMANCE: CO Approval – October 31, 2014

I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) National Center for Environmental Assessment (NCEA) through the conduct of a needs assessment that will identify and evaluate demand for toxicity assessments prepared by the Integrated Risk Information System (IRIS) Program. Activities within this work assignment will be broken down into three phases and will include soliciting, gathering, organizing, summarizing, analyzing, and synthesizing information from EPA's internal and external stakeholders concerning their demand for new and revised IRIS toxicological assessments and developing a final report, which will include estimating EPA resources required to meet the demand for IRIS toxicological assessments. Internal stakeholders include EPA's Program and Regional Offices. External stakeholders include other federal agencies, state/local governments, and the public. This task is being undertaken in response to recommendations made by the U.S. Government Accountability Office (GAO) in their May 2013 report (GAO-13-396) titled, *Chemical Assessment: An Agency-wide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information Assessments*.

II. BACKGROUND

EPA's IRIS Program develops peer-reviewed toxicological assessments that evaluate qualitative (hazard) and quantitative (dose-response) information on human health effects that may result from exposure to specific chemical substances found in the environment. IRIS assessments are widely used by EPA's programs and regions as a critical part of the scientific foundation of regulatory activities and risk management decisions. Additionally, other federal government and private entities will often combine IRIS toxicity values with specific exposure information to help characterize public health risks of exposure to chemical substances in a site-specific situation. The IRIS database contains information on more than 550 chemical substances that can be used to support the first two steps (hazard identification and dose-response assessment) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects, and oral slope factors and/or inhalation unit risks for cancer effects.

In September 2003, EPA published the results of an evaluation of demand for IRIS toxicity assessments titled, *Needs Assessment for U.S. EPA's Integrated Risk Information System*. The evaluation included input from IRIS users both inside and outside of EPA, and estimated that 50 new or updated IRIS toxicity assessments were needed each year to meet IRIS user's needs. However, GAO's May 2013 *Chemical Assessment* report did not find sufficient support for this estimate, and recommended that EPA identify and evaluate current demand for IRIS toxicity assessments by undertaking a new needs assessment. Additionally, in 2008, EPA released a report

titled, Development of an Analytic Approach to Determine How Environmental Protection Agency's Integrated Risk Information System (IRIS) Is Used By Non EPA Decision Makers (January 10, 2008), which describes how IRIS is used by a small number of representative groups of users outside of EPA. Both the 2003 needs assessment and 2008 analytic approach documents will be provided to the Contractor to assist in identifying IRIS users outside EPA for this new needs assessment.

III. STATEMENT OF WORK

A. Objective

This work assignment will support EPA in responding to the GAO's recommendations to: (1) identify and evaluate demand for IRIS toxicity assessments, and (2) estimate EPA resources required to meet that demand. Using a three-phased approach, the Contractor shall:

- Phase 1: Assess the needs of EPA's program and regional offices for IRIS toxicological assessments.
- Phase 2: Assess the needs of EPA's external stakeholders, such as other federal agencies, state and local governments, and the public, for IRIS toxicological assessments.
- Phase 3: Produce a report summarizing the needs of EPA's internal and external stakeholders for IRIS toxicological assessments, including the resources necessary to meet this demand.

The primary activities to be undertaken during Phase 1 include:

- 1) Upon award of the work assignment, host an initial conference call with the EPA Work Assignment Manager (WAM) prior to commencing work to discuss possible analytical approaches and the scope of IRIS users who will be included in the needs assessment.
- 2) Develop an analytical approach to solicit information from multiple internal and external EPA stakeholders regarding their need for IRIS toxicological assessments.
- 3) Prior to commencing data solicitation, host a conference call with the EPA WAM to discuss the analytical approach developed to solicit and organize the information collected on internal and external EPA stakeholder IRIS needs. Collect data from EPA <u>internal</u> IRIS users (i.e., EPA's program and regional offices).
- 4) Review, organize, analyze, synthesize, and summarize the responses provided by internal EPA stakeholders to determine the number of IRIS assessments needed and for what purpose they are needed.
- 5) Prepare and deliver to the EPA WAM a Phase 1 report assessing the needs of EPA's program and regional offices for IRIS toxicological assessments.

The primary activities to be undertaken during Phase 2 include:

- 6) Revisit the analytical approach developed to ensure that lessons learned from Phase 1 are addressed in Phase 2.
- 7) Prior to commencing data solicitation from <u>external</u> stakeholders, host a conference call with the EPA WAM to discuss the revised analytical approach to solicit and organize the information collected from external EPA stakeholders regarding their need for IRIS toxicological assessments and to clarify the scope of external stakeholders that will be included in the Phase 2 assessment.
- 8) Collect data from EPA's external IRIS stakeholders, within the agreed upon scope.
- 9) Review, organize, analyze, synthesize, and summarize the responses provided by external EPA stakeholders to determine the number of IRIS assessments needed and for what purpose they are needed.

10) Prepare and deliver to the EPA WAM a Phase 2 report assessing the needs of EPA's external stakeholders for IRIS toxicological assessments.

The primary activities to be undertaken during Phase 3 include:

- 11) Once the needs of EPA's internal and external stakeholders have been assessed, the contractor shall estimate the resources necessary for EPA to meet the identified demand.
- 12) Prepare and deliver to the EPA WAM a draft report summarizing the input received from EPA's internal and external stakeholders regarding their need for IRIS toxicological assessments and making recommendations to EPA on what changes can be made to ensure a sustainable IRIS Program that meets users' needs for toxicity assessments, given the resources required to meet user's needs and identified EPA resources constraints.
- 13) Prepare and deliver to the EPA WAM a final report in hard copy and in electronic format in Microsoft Office Word 2007 or higher.

To assist the Contractor in preparing their Technical and Cost Proposal, EPA will make available to the Contractor through the EPA WAM information collected in June 2013 from EPA's program and regional offices regarding their need for new and updated IRIS toxicological assessments. In addition, the EPA WAM will provide access to EPA's 2003 report titled, *Needs Assessment for U.S. EPA's Integrated Risk Information System* and the 2008 report titled, *Development of an Analytic Approach to Determine How Environmental Protection Agency's Integrated Risk Information System (IRIS) Is Used By Non EPA Decision Makers*.

B. Definition of Tasks

Task 1: Establish Communication

Within 3 days of the start date of this Performance Work Statement, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate Contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. A similar call will be scheduled at the beginning of each phase of work over the course of this work assignment.

Task 2: Technical Work Plan, including Staffing and Costs

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of organizational behavior, business process operations and optimization, survey research and analysis, systems science, stakeholder engagement, and management sciences. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

Task 3: Complete Primary Activities 1-2, including development of analytical approach

Upon completion of the Kick-Off Conference Call, the Contractor shall complete Primary Activities 1-2 outlined above and deliver to the EPA WAM a document describing the analytical approached the Contractor intends to employ in soliciting information from multiple internal and external EPA stakeholders regarding their need for IRIS toxicological assessments. In completing Primary Activities 1-2, EPA will provide technical direction. The EPA WAM will submit comments on the primary task deliverable, the analytical approach document, within 14 days of receiving this draft document. The Contractor shall revise the deliverable based on

the EPA WAM's comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. This task will be completed when all comments from the EPA WAM have been considered and addressed, and may require multiple rounds of revision. The Contractor shall prepare and forward a revised document to the EPA WAM within 7 days of receipt of the EPA WAM's final comments on the deliverable.

Task 4: Complete Primary Activities 3-5, including preparation of a Phase 1 report assessing the needs of EPA's program and regional offices for IRIS toxicological assessments

Prior to commencing data solicitation under Primary Activity 3, the Contractor shall host a conference call with the EPA WAM to discuss the analytical approach developed to solicit and organize the information on internal and external EPA stakeholder IRIS needs. Upon EPA WAM approval of Primary Activity 2 and completion of this conference call, the Contractor shall complete Primary Activities 3-5 as outlined above and prepare a Phase 1 report assessing the needs of EPA's program and regional offices for IRIS toxicological assessments. In completing primary activities 3-5, EPA will provide technical direction on the most appropriate way to organize input on IRIS needs. The EPA WAM will submit comments on the primary task deliverable, the Phase 1 report, within 14 days of receiving the draft report. The Contractor shall revise the deliverable based on the EPA WAM's comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. This task will be completed when all comments from the EPA WAM have been considered and addressed, and may require multiple rounds of revision. The Contractor shall prepare and forward a revised document to the EPA WAM within 7 days of receipt of the EPA WAM's final comments on the deliverable.

Task 5: Complete Primary Activities 6-10, including preparation of a Phase 2 report assessing the needs of EPA's external stakeholders for IRIS toxicological assessments

Upon completion of Phase 1 (i.e., Primary Activities 1-5), the Contractor shall complete Primary Activities 6-10 under Phase 2, outlined above in *Section III*. *Statement of Work*, and prepare a Phase 2 report assessing the needs of EPA's external stakeholders for IRIS toxicological assessments. In completing Primary Activities 6-10, EPA will provide technical direction on the most appropriate way to organize public input on IRIS needs. The EPA WAM will submit comments on the primary task deliverable, the Phase 2 report, within 14 days of receiving the draft report. The Contractor shall revise the deliverable based on the EPA WAM's comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. This task will be completed when all comments from the EPA WAM have been considered and addressed, and may require multiple rounds of revision. The Contractor shall prepare and forward a revised document to the EPA WAM within 7 days of receipt of the EPA WAM's final comments on the deliverable.

Task 6: Complete Primary Activities 11-13, including preparation of a final report

Upon completion of Phase 2 (i.e., Primary Activities 6-10), the Contractor shall complete Primary Activities 11-13 under Phase 3, outlined above in *Section III. Statement of Work*, and prepare a final report summarizing the input received from EPA's internal and external stakeholders regarding their need for IRIS toxicological assessments and making recommendations to EPA on what changes can be made to ensure a sustainable IRIS Program that meets users' needs for toxicity assessments, given the resources required to meet user's needs and identified EPA resource constraints. In completing Primary Activities 11-12, EPA will provide technical direction and documentation to assist the contractor in estimating the EPA resources necessary to meet IRIS user needs. The EPA WAM will submit comments on the primary task deliverable, the final report, within 14 days of receiving the draft report. The Contractor shall revise the deliverable based on the EPA WAM's comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. This task will be completed when all comments from the EPA WAM have been considered and

addressed, and may require multiple rounds of revision. The Contractor shall prepare and forward a revised document to the EPA WAM within 14 days after final comments on the draft report are provided by EPA. The Contractor shall submit five copies of the final report to the EPA WAM. An electronic copy in Microsoft Office Word 2007 or higher shall also be submitted.

IV. ANTICIPATED DELIVERABLES

- Task 1. Kick-off Conference Call
- Task 2. Technical Work Plan, including Staffing and Costs
- Task 3. Analytical Approach Document
- Task 4. Phase 1 Report Internal Stakeholder IRIS Needs assessment
- Task 5. Phase 2 Report External Stakeholder IRIS Needs Assessment
- Task 6. Final Report

All deliverables shall consist of electronic versions of written documents in Microsoft Word 2007 or higher, and should include, when appropriate, a "redline" (track changes) version in addition to the "clean" draft.

V. SCHEDULE OF DELIVERABLES

All deliverables shall be provided in electronic format in Microsoft Word 2007 or higher; "Track Changes" redline/strikeout shall be employed throughout the revision process.

DELIVERABLE	SCHEDULE
Kick-off Conference Call (Task 1)	2 days after receipt of approved Technical and Cost Proposal
Technical Work Plan (Task 2)	In accordance with the contract
Complete Primary Activities 1-3 and prepare Analytical Approach Document (Task 3)	30 days after approval of Technical Work Plan
Complete Primary Activities 4-5 and prepare Phase 1 report (Task 4)	60 days after completion of Task 3 and receipt of Technical Direction for Task 4
Revision of primary task deliverable (Task 4)	14 days after WAM approves Task 4 draft report
Complete primary activities 6- 10 and prepare Phase 2 report (Task 5)	90 days after completion of Task 4 and receipt of Technical Direction for Task 5 draft report
Revision of primary task deliverable (Task 5)	14 days after WAM approves Task 5
Complete Primary Activities 11-13 and prepare final report (Task 6)	60 days after completion of Task 5 and receipt of Technical Direction for Task 6

Final Report (Task 6)	21 days after WAM approves revised draft report

^{*}All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in the contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- 1. Formulation of Agency policy
- 2. Selection of Agency priorities
- 3. Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO or WAM.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO or WAM.

WORK ASSIGNMENT MANAGER (WAM):

Ted Berner

Telephone: (703) 347-8583

Fax: (703) 347-8689

E-mail: berner.ted@epa.gov

Mailing Address:

U.S. Environmental Protection Agency

Office of Research and Development

National Center for Environmental Assessment (Mail Code: 8601P)

1200 Pennsylvania Ave NW Washington,

DC 20460

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-02

TITLE: Toxcast Data Release Workshops and Data Summit

Specify Section & Paragraph SOW: E. Risk Assessment Support

PERIOD OF PERFORMANCE: CO Approval - October 31, 2014

I. PURPOSE:

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for two face-to-face Stakeholder Workshops and one Stakeholder Data Summit. The Stakeholder Workshops will be held in the Washington, DC area and/or in Research Triangle Park, NC. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND:

Recent advances in chemical safety research provide innovative solutions to persistent and pervasive issues facing risk assessments and policy decisions made about the safety of chemicals. To address some of these issues, EPA's chemical safety research has been using advances in computational toxicology to begin addressing the significant lack of health and environmental data on the thousands of chemicals. This computational toxicology research integrates advances in molecular biology, chemistry, toxicology, exposure science and computer science to more effectively and efficiently rank chemicals for potential risk.

Since 2005, EPA researchers have generated massive amounts of hazard data on thousands chemicals, designed innovative chemical exposure prediction models and created a repository of thousands of high quality chemical structure data. Using advances in computer science, these data sources can be searched and queried together to help predict the potential risks of chemicals to human health. Policy makers and stakeholders can access this data and developed models to help inform decisions they make about chemicals. However, because the chemical data is so massive and new, there are data translation, accessibility and usage challenges. These challenges can begin to be addressed by implementing outreach and engagement activities targeting stakeholder groups. One outreach strategy EPA plans to use to help with data translation, accessibility and usability challenges are face-to-face workshops for external stakeholders who have an interest in using this new data to inform decisions made about chemical safety.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a series of three (3) meetings in the form of two workshops and a Data Summit meeting. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a summary report (including meeting and breakout discussion notes), communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The workshop dates are January 14-15, 2013 (Research Triangle Park, NC) and February (days TBD) 2013 (Potomac Yards in DC). EPA anticipates having approximately 100 workshop participants. The Data Summit will be held May 13-14, 2014 in Research Triangle Park, NC and EPA anticipates having 100-200 participants. This work

assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has or will reserve its own meeting room space for these workshops. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for workshop and Data Summit planning may include:
 - A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
 - Develop a registration mechanism and coordinating registration, including maintaining a list of participants.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Preparing folders for distribution to attendees at registration including final agenda, meeting roster, survey for participants to fill out, name badges and other meeting materials.
 - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
 - Setting up webinar, conference call and if applicable video conference capability for remote participation.

3. Onsite Logistical Support and Reporting

- Providing staff to support the workshops and the data summit onsite.
- Facilitating discussions during the plenary group sessions. Facilitation is needed to encourage full participation and to keep the group on track to accomplish meeting objectives. The facilitator must have the knowledge and skill to intervene in a technical discussion in a way that adds value and encourages creativity.
- Capturing notes during the discussion including the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
- Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
- Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.
- Distribute and collect the workshop and data summit surveys from participants.
- Summarize in a report all meeting discussions including key decisions and actions items in a post-meeting summary report. This report should include a listing of all meeting attendees.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Initial contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	December 9 th , 2013
Submit electronic copies of registration lists and registration materials;	Two working days before each workshop
Submit updated list of registered attendees, electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following each workshop and Data Summit
Post-workshop final report(s)	Ten working days following each workshop in January 2013 and February 2014
Post-data summit final report	Ten working days after the Data Summit in May 2014

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Monica Linnenbrink 919-541-1522 <u>Linnenbrink.Monica@epa.gov</u>

Alternate WAM
Michael Loughran
202-564-6686
Loughran.Michael@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-02 Amend 1

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Specify Section & Paragraph SOW: E. Risk Assessment Support

TITLE: Toxcast Data Release Workshops and Data Summit

PERIOD OF PERFORMANCE: CO Approval – October 31, 2014

This Amendment is address the changes for Workshop as follows:

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a series of three (3) meetings in the form of two workshops and a Data Summit meeting. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a summary report (including meeting and breakout discussion notes), communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The workshop dates are January 14-15, 2014 (Research Triangle Park, NC) and April 2-3, 2014 (Potomac Yards in DC). EPA anticipates having approximately 100 workshop participants. *The Data Summit has been rescheduled and will be held September 29-30, 2014* in Research Triangle Park, NC and EPA anticipates having 100-200 participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has or will reserve its own meeting room space for these workshops. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for workshop and Data Summit planning may include:
 - Provide travel support to select (non-federal) external stakeholders selected to give presentations at the Data Summit. The names of the invited speakers will be made available by August 1st, 2014.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date				
Provide travel logistics support for invited stakeholders	Update provided by September 9th, 2014				
Post-data summit final report	Ten working days after the Data Summit in September 2014				

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PERFORMANCE WORK STATEMENT Contract No. EP-C-14-001

WA 0-03

Title: IRIS Public Stakeholder Meeting – Literature Searches, Evidence Tables, Exposure Response Arrays, and Draft Assessments

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO award – October 31, 2014

I. <u>PURPOSE</u>

The purpose of this work assignment is to provide administrative and logistical support to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) for a two day public meeting on December 12-13, 2013. The meeting will be held in EPA conference space at Potomac Yard One, 2777 S. Crystal Drive, Arlington, VA 22202. The meeting will focus on public comments on draft preliminary materials (literature searches, evidence tables and exposure response arrays) for *tert*-butyl alcohol (*tert*-butanol), ethyl-*tert*-butyl ether (ETBE), and hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) and the draft IRIS assessments on ethylene oxide (EtO) and benzo[a]pyrene (BaP). EPA has released these documents for public comment. The purpose of the meeting is to give the public an opportunity to provide input and engage with EPA in a dialogue about the chemicals.

II. <u>BACKGROUND</u>

The EPA NCEA is part of the Office of Research and Development (ORD). EPA's Integrated Risk Information System (IRIS) program is housed within NCEA. The IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health and the environment.

Public meetings will be held approximately every 2 months. Materials for the public meetings are posted on the IRIS website (http://www.epa.gov/iris/publicmeeting/). The meetings provide an opportunity for the public to provide input on preliminary materials prior to development of the draft assessment and provide input on drafts of assessments and charges to the peer review panels prior to external peer review. In step 1 of the IRIS process (development of the draft assessment), EPA releases preliminary materials comprised of draft literature search strategies describing the processes for identifying and screening scientific literature and the literature search results, and preliminary evidence tables and preliminary exposure-response arrays summarizing key characteristics and findings from critical studies that EPA proposes to consider in developing IRIS assessments. In step 4 of the IRIS process (public review and comment/independent expert peer review), EPA

releases the draft assessment and draft peer review charge for public comment and also holds a public meeting to discuss these materials. The meeting support covered by this PWS is for three chemicals in step 1 (*tert*-butyl alcohol (*tert*-butanol), ethyl-*tert*-butyl ether (ETBE), and hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)) and two chemicals in step 4 (ethylene oxide (EtO) and benzo[a]pyrene (BaP).

EPA welcomes all comments on the draft literature search strategies, preliminary evidence tables, preliminary exposure-response arrays, and draft assessment that will be discussed in this public meeting. In particular, EPA welcomes comments on the clarity and transparency of the materials, the approach for identifying pertinent literature, the selection of studies for data extraction to preliminary evidence tables and exposure-response arrays, methodological considerations that could affect the interpretation of or confidence in study results, and additional studies published or nearing publication that may provide data for assessment development. The IRIS Program believes that public involvement can be most beneficial at the early stages of developing an assessment. Releasing the draft literature search strategy, evidence tables, and exposure response arrays early will ensure that critical research is not omitted and communicates to the public why critical studies were chosen for further evaluation, helping frame major scientific issues and ultimately leading to more efficient production of assessments.

III. STATEMENT OF WORK

A. Objective

The overall objective of this work assignment (WA) is to provide meeting facilitation, and administrative and logistical support for the December 12-13, 2013 public meeting described above. The meeting will be held in EPA conference space at the Potomac Yard One Conference Facility on 2733 S. Crystal Drive, Arlington, VA 22202. EPA has established a website to facilitate registration by members of the public that wish to attend the meeting. This public meeting shall include access by webinar and teleconference lines. Stakeholders and members of the public have been invited to request time on the agenda to make presentations as well as participate in an open dialogue on the meeting materials related to these IRIS chemicals. It is expected that the public meeting will consist of 5 sessions with each session focusing on one of the 5 chemicals. The amount of time allocated to each chemical will depend on the number of persons requesting time to make presentations and the extent of comments provided on each chemical. The Contractor shall provide assistance (including onsite assistance) to EPA prior to, during, and immediately after, the public meeting. Facilitation administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks)

1. Establish Communication Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

2. Support Provided Before the December 12-13, 2013 Public Meeting

- a. Making arrangements for the public to participate in the meeting through a teleconference line.
- b. Coordinating with Potomac Yard Conference Center AV and IT support to ensure adequate telephone and internet connections will be available at meeting location and ensuring AV equipment is available and setup before the public meeting.
- c. Making copies of the meeting agenda, and other meeting materials for distribution on the meeting dates.
- d. Monitoring the EPA registration website and compiling and maintaining the meeting registration list and presentation materials submitted by the public. Providing a full registration list on November 15, 2013 and an updated list on Dec 6, 2013.
- e. Providing EPA security a list of attendees the day before the meeting.
- f. Managing the collection of presentations from the public and EPA and preparation of electronic files needed during the public meeting. Loading all public and EPA presentations on the computer to be used during public meeting.
- g. Making arrangements for sign-in table and meeting agenda distribution on day of the meeting.
- h. Conduct up to two dry-runs for the webinar and physical room set-up including operation of all AV equipment, internet connections, and computer presentations to be used in the meeting. May include set-up of cameras, sound equipment, computer locations in room, and webinar room. Dry-runs would be conducted on Dec. 2, 2013 and Dec 11, 2013 at times specified by the EPA WAM.

3. Support Provide During the Meeting

- a. Staffing sign-in table, distributing meeting Agenda on meeting days.
- b. Providing name tents for key EPA personnel participating in the meeting.
- c. Webinar support including, but not limited to:
 - 1) Addressing technical difficulties raised by webinar participants.
 - 2) Organizing the presentation transitions between speakers.
 - 3) Monitoring and handling questions/comments from online participants and reporting those questions at the public meeting.
 - 4) Handling any audio/video issues or needs provided for online participants, including webcam video feeds.
- d. Establish teleconference line connection approximately 30 minutes before meeting start.
- e. Provide on-site meeting facilitation to promote adherence to schedule, and a balanced opportunity for public participation from those attending within the room, and via webinar and teleconference line. Contractor will report webinar questions to the meeting attendees in the room and on the conference line. EPA will provide facilitation of the scientific dialogue to ensure issues are appropriately addressed but the contractor is responsible for overall meeting facilitation.

4. Support After the Meeting

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. Provide notes, statistics, questions and poll results from webinar.

IV. SCHEDULE OF DELIVERABLES

Deliverables	Due Dates

1.	Teleconference NTE 1 hr - outlining how all tasks (listed above) shall be performed.	1.	Within 3 days of award
2.	Submit electronic copies of registration list and presentations submitted by the public to EPA WAM	2.	November 15, December 6, 2013
3.	Schedule Teleconference Lines	3.	Dec 2, 2013
4.	Conduct first dry run at Potomac Yard One, Arlington VA.	4.	Dec 2, 2013
5.	Conduct second dry run including webinar and AV at Potomac Yard One, Arlington VA.	5.	Dec 11, 2013
	and 117 at 1 otomice 1 and one, 1 mington 171.	6.	Dec 11, 2013
6.	Submit final list of registered attendees to EPA security for Potomac Yard One		
		7.	Dec 11-13, 2013
7.	Webinar support, meeting facilitation, sign-in table, teleconference lines		
8.	Provide registration/attendance list and	8.	Dec 17, 2013

V. SPECIAL CONDITIONS AND ASSUMPTIONS

webinar statistics and info

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VI. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Amanda Boone-Edwards 703-347-8654 boone-edwards.amanda@epa.gov

EPA	United States Environm Washin	ental Protection gton, DC 20460	Work Assignment Number 0-03								
EFA	Work A	ssignment		Other X Amendment Number							
Contract Number	Contract Period 11/	′01/2013 To	10/31/	2014	Title of Work Assignment/SF Site Name						
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PERFORMANCE WORK STATEMENT Contract No. EP-C-14-001 WA 0-03 Amend 1

Title: IRIS Public Stakeholder Meeting – Literature Searches, Evidence Tables, Exposure Response Arrays, and Scoping/Problem Formulation

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO award – October 31, 2014

I. PURPOSE

The purpose of this work assignment amendment is to add the requirement to provide administrative and logistical support to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) for a two day public meeting/workshop on April 23-24, 2014 and one additional 2 day public meeting to be held on June 25-26, 2014 or September 3-4 2014. The meetings will be held in EPA conference space at Potomac Yard One, 2777 S. Crystal Drive, Arlington, VA 22202. If meeting space on EPA campus becomes unavailable, the contractor will be advised through written technical direction to secure commercial meeting space. The April meeting will focus on public comments on draft preliminary materials (literature searches, evidence tables, and exposure response arrays) for arsenic, diethyl phthalate (DEP) and hexabromocyclododecane (HBCD), and preliminary materials (problem formulation materials such as xxx) for DIPE, ethylbenzene, hexachlorobutadiene (HCBD), napthalene, and TAME/TAEE. EPA will release these materials for public comment approximately 60 days before the meeting. The June or September meeting will focus on IRIS chemicals currently undergoing assessment and will be specified to the contractor approximately 90 days before the meeting. The purpose of the meeting is to give the public, and experts with extensive knowledge about issues related to the assessment of potential health hazards associated with the chemicals, an opportunity to provide input to EPA and to engage in a dialogue about such issues.

II. BACKGROUND

The EPA NCEA is part of the Office of Research and Development (ORD). EPA's Integrated Risk Information System (IRIS) program is housed within NCEA. The IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health and the environment.

Public meetings will be held approximately every 2 months. Materials for the public meetings are posted on the IRIS website (http://www.epa.gov/iris/publicmeeting/). The meetings provide an opportunity for the public to provide input on preliminary materials prior to development of the draft assessment and drafts of assessments and charges to the peer review panels prior to external peer review. In step 1 of the IRIS process (development of the draft assessment), EPA releases preliminary materials comprised of problem formulation information, draft literature search strategies describing the processes for identifying and screening scientific literature and the literature search results, and preliminary evidence tables and preliminary exposure-response arrays summarizing key characteristics and findings from critical studies that EPA proposes to consider in developing IRIS assessments. In step 4 of the IRIS process (public review and comment/independent expert peer review), EPA releases the draft assessment and draft peer review charge for public comment and also holds a public meeting to discuss these materials. The meeting support covered by this PWS is for chemicals for which literature searches, evidence tables, and exposure response arrays, and/or scoping or problem formulation information will be released approximately 60 days before the meetings.

EPA welcomes all comments on the draft literature search strategies, preliminary evidence tables, preliminary exposure-response arrays, and the scoping and problem formulation information that will be discussed in these public meetings. In particular, EPA welcomes comments on the clarity and transparency of the materials, the approach for identifying pertinent literature, the selection of studies for data extraction to preliminary evidence tables and exposure-response arrays, methodological considerations that could affect the interpretation of or confidence in study results, and additional studies published or nearing publication that may provide data for assessment development. The IRIS Program believes that public involvement can be most beneficial at the early stages of developing an assessment. Releasing the draft scoping, problem formulation information, literature search strategies, evidence tables, and exposure response arrays early will ensure that critical research is not omitted and communicates to the public why critical studies were chosen for further evaluation, helping frame major scientific issues and ultimately leading to more efficient production of assessments.

III. STATEMENT OF WORK

A. Objective

The overall objective of this work assignment (WA) is to provide meeting facilitation, and administrative and logistical support for the April 23-24, 2014 public meeting described above and one additional meeting to occur on June 25-26, 2014 or September 3-4, 2014. The meetings will be held in EPA conference space at the Potomac Yard One Conference Facility on 2733 S. Crystal Drive, Arlington, VA 22202 or in commercial meeting space to be provided by the contractor. The contract shall EPA has established a website to facilitate registration by members of the public that wish to attend the meeting. The public meetings shall include access by webinar and teleconference lines. Stakeholders and members of the public have been invited to request time on the agenda to make presentations as well as participate in an open dialogue on the meeting materials related to these IRIS chemicals. The contractor shall be responsible for collection of presentation materials from all speakers on the agenda including EPA and all stakeholders, public and private. It is expected that the public meetings will consist of 3-5 sessions with each session focusing on one of the chemicals or groups of chemicals. The amount of time allocated to each chemical will depend on the number of persons requesting time to make presentations and the extent of comments provided on each chemical. The Contractor shall provide assistance (including onsite assistance) to EPA prior to, during, and immediately after, the public meeting. Facilitation administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks)

1. Establish Communication Within 3 days of start date of this WA Amendment, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates. The contractor shall prepare a separate line item in the work plan to include pricing for non-EPA space if necessary.

2. Support Provided Before the Public Meeting

- a. The meeting will be held in EPA conference space in Potomac Yard, Arlington VA., or if directed by the WAM, the contractor shall be responsible for arranging appropriate meeting facilities in the Washington, DC area. The meeting room should be large enough to accommodate a panel of 10-15 speakers and up to 100 attendees in the audience. Panel members should be seated at a table in the front of the room with ample room for their presentation materials and microphones provided. A podium with microphone will also be provided for presenters. A table arrangement that facilitates interaction between the panel members and with members of the audience that wish to provide comments or participate in the discussion is preferred. The site must conform to Federal off-site meeting requirements. The contractor shall obtain the approval of the WAM before entering into an agreement for a meeting location. Audiovisual equipment, a laptop computer and projector for presentations, webinar and teleconference equipment that facilitates remote presentations and participation, microphones for audience participation and any other equipment needed to conduct the meeting shall be the responsibility of the contractor.
- b. Establish and implement meeting registration procedures and website. Registration procedures will include on-line registration via the contractor established website and e-mail/telephone to the contractor's meeting contact. Such procedures will require presenters to submit presentations to the contractor and the specified docket simultaneously and accommodate late registrants. The contractor will closely monitor registration status and compile and maintain the meeting registration list and presentation materials submitted by the public. The contractor will provide weekly updates on registration status beginning one week after registration opens.
- c. Making arrangements for the public to participate in the meeting through a webinar and teleconference line.
- d. If the meeting is held in Potomac Yard conference space, the contractor is responsible for coordinating with Potomac Yard Conference Center AV and IT support to ensure adequate telephone and internet connections will be available at meeting location and ensuring AV equipment is available and setup before the public meeting, and providing EPA security a list of attendees the day before the meeting.

- e. Making copies of the meeting agenda, and providing name tents for panelists, and other meeting materials for distribution on the meeting dates. Making arrangements for sign-in table and meeting agenda distribution on day of the meeting.
- f. Managing the collection of presentations from the public and EPA and preparation of electronic files needed during the public meeting. Loading all public and EPA presentations on the computer to be used during public meeting.
- g. If the meeting is held in EPA space, conduct up to two dry-runs for the webinar and physical room set-up including operation of all AV equipment, internet connections, and computer presentations to be used in the meeting. May include set-up of cameras, sound equipment, computer locations in room, and webinar room. One or more dry-runs will be conducted within a 2 week time period of the public meeting date when EPA conference space can be made available.

3. Support Provided During the Meeting

- a. Staffing sign-in table, distributing meeting Agenda on meeting days.
- b. Providing name tents for EPA personnel and public participants that will serve on a panel.
- c. Webinar support including, but not limited to:
 - 1) Addressing technical difficulties raised by webinar participants.
 - 2) Organizing the presentation transitions between speakers.
 - 3) Monitoring and handling questions/comments from online participants and reporting those questions at the public meeting.
 - 4) Handling any audio/video issues or needs provided for online participants, including webcam video feeds.
- d. Establish teleconference line connection approximately 30 minutes before meeting start.
- e. Provide on-site meeting facilitation to promote adherence to schedule, and a balanced opportunity for public participation from those attending within the room, and via webinar and teleconference line. Contractor will report webinar questions to the meeting attendees in the room and on the conference line. EPA will provide facilitation of the scientific dialogue to ensure issues are appropriately addressed but the contractor is responsible for overall meeting facilitation.

4. Support After the Meeting

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. Provide notes, statistics, questions and poll results from webinar.

IV. SCHEDULE OF DELIVERABLES

	Deliverables	Due Dates
1	Teleconference NTE 1 hr - outlining how all tasks (listed above) shall be performed.	Within 3 days of award
2	If meeting is to be held in commercial meeting space – submit meeting location and space configuration options to WAM for approval prior to entering into any agreement for space.	No later than 1 week of notification by WAM that the meeting must be held in commercial space.
3	Submit proposed registration website design and registration procedures (including late registration and notification packet to be sent to attendees) to WAM for approval.	No later than 1 week after deliverable teleconference
4	Open approved registration website to the public.	Approximately 60 days before the public meeting date.
5	Submit electronic copies of registration list to EPA WAM.	Weekly beginning with closure of registration and until the public meetin date
6	Provide EPA WAM presentations submitted by the public.	No later than 1 day of receipt from presenter.
7	Schedule teleconference lines and webinar room of sufficient size to accommodated registrants plus 20%.	No later than 1 week before meeting
8	If meeting held at Potomac Yard - Conduct dry run at Potomac Yard One, Arlington VA., including webinar and operation of AV equipment.	Within a 2 week time period before the public meeting date.
9	If needed, conduct second dry run at Potomac Yard One, Arlington VA	Within a 2 week time period before the public meeting date.
10	If meeting is held at Potomac Yard - submit final list of registered attendees to EPA security for Potomac Yard One	One day before the public meeting.
11	Webinar support, meeting facilitation, sign-in table, teleconference lines	During 2 day public meeting.

12 Provide registration/attendance list and webinar statistics and info to WAM	Within 1 week after the public meeting is adjourned.

V. <u>SPECIAL CONDITIONS AND ASSUMPTIONS</u>

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VI. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM): Amanda Boone-Edwards 703-347-8654 boone-edwards.amanda@epa.gov

			Uni	United States Environmental Protection Agency						Work Assignment Number					
EPA			Washington, DC 20460						0-03						
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PERFORMANCE WORK STATEMENT Contract No. EP-C-14-001 WA 0-03 Amend 2

Title: IRIS Public Stakeholder Meeting – Literature Searches, Evidence Tables, Exposure Response Arrays, and Scoping/Problem Formulation

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO award - October 31, 2014

This amendment is to add a Note Taker:

3. Support Provided During the Meeting

f. Taking notes of the major issues discussed at the meeting sufficient to allow preparation of a general meeting summary suitable for posting on the IRIS website. Details of individual speakers' comments are not needed. Rather, a general summary of the issues discussed and the range of opinions expressed should be captured. In addition, any commitments of future action made by EPA representatives should be noted to facilitate follow-up by EPA after the meeting.

g. Support After the Meeting

c. Provide a general meeting summary for posting on EPA's IRIS website.

IV. SCHEDULE OF DELIVERABLES

	Deliverables	Due Dates
13	Provide a general meeting summary for posting on EPA's IRIS website.	Within 1 week after the public meeting is adjourned.

	United States Environmenta	al Protection Agency	Work Assignment Number				
EDA	Washington	1-0	0-03				
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(Signature)		(Date)	FAX Number:				
Project Officer Name Melissa Rev	ely-Wilson	Branch/Mail Code:					
	Phone Number: 703-347-8523						
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PERFORMANCE WORK STATEMENT Contract No. EP-C-14-001 Amend 4

Title: IRIS Public Stakeholder Meeting – *Scoping and Problem Formulation*, Literature Searches, Evidence Tables, Exposure Response Arrays, and Draft Assessments

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO award - October 31, 2014

NOTE: Changes in this amendment can be identified in Bold Italics.

I. PURPOSE

The purpose of this work assignment is to provide administrative and logistical support to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA) for *three* public meetings and a workshop on September 3-4, 2014, *October 15-16, 2014* and October 29-30, 2014. The meetings will be held in EPA conference space at Potomac Yard One, 2777 S. Crystal Drive, Arlington, VA 22202. The meetings will focus on public comments on draft preliminary materials (problem formulation, literature searches, evidence tables, exposure response arrays) for selected chemicals and draft IRIS assessments on selected chemicals, *and the October 15-16 workshop will focus on a recent NAS recommendations for implementation of the IRIS program*. EPA will released all meeting materials before the meeting. The purpose of the meetings is to give the public an opportunity to provide input and engage with EPA in a dialogue about the chemicals under review *and the 2014 NRC report on the IRIS program*.

II. BACKGROUND

The EPA NCEA is part of the Office of Research and Development (ORD). EPA's Integrated Risk Information System (IRIS) program is housed within NCEA. The IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health. The IRIS database contains information for more than 500 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the human health risk assessment process. When supported by available data, IRIS provides health effects information and toxicity values for health effects (including cancer and effects other than cancer). Government and others combine IRIS toxicity values with exposure information to characterize public health risks of chemical substances; this information is then used to support risk management decisions designed to protect public health and the environment. The National Research Council issued a report on the IRIS program in July 2014 which will be discussed at the October 15-16, 2014 workshop.

Public meetings and workshop will be held on the dates specified. Materials for the public meetings and workshop are posted on the IRIS website (http://www.epa.gov/iris/publicmeeting/). The meetings provide an opportunity for the public to provide input on preliminary materials prior to development of the draft assessment and provide input on drafts of assessments and charges to the peer review panels prior to external peer review or to provide input regarding the 2014 NRC recommendations on the IRIS program. In step 0 of

the IRIS process EPA releases scoping and problem formulation materials. In step 1 of the IRIS process (development of the draft assessment), EPA releases preliminary materials comprised of draft literature search strategies describing the processes for identifying and screening scientific literature and the literature search results, and preliminary evidence tables and preliminary exposure-response arrays summarizing key characteristics and findings from critical studies that EPA proposes to consider in developing IRIS assessments. In step 4 of the IRIS process (public review and comment/independent expert peer review), EPA releases the draft assessment and draft peer review charge for public comment and also holds a public meeting to discuss these materials. The meeting support covered by this PWS is for the chemicals EPA designates approximately 60 days before the public meeting and for meeting materials related to the recommendations contained in the 2014 NRC report on IRIS..

EPA welcomes all comments on the draft literature search strategies, preliminary evidence tables, preliminary exposure-response arrays, draft assessments and implementation issues that will be discussed in the public meeting and NRC workshop. In particular, EPA welcomes comments on the clarity and transparency of the materials, the approach for identifying pertinent literature, the selection of studies for data extraction to preliminary evidence tables and exposure-response arrays, methodological considerations that could affect the interpretation of or confidence in study results, and additional studies published or nearing publication that may provide data for assessment development. The IRIS Program believes that public involvement can be most beneficial at the early stages of developing an assessment. Releasing the draft literature search strategy, evidence tables, and exposure response arrays early will ensure that critical research is not omitted and communicates to the public why critical studies were chosen for further evaluation, helping frame major scientific issues and ultimately leading to more efficient production of assessments.

III. STATEMENT OF WORK

A. Objective

The overall objective of this work assignment (WA) is to provide meeting facilitation, and administrative and logistical support for the September 3-4, 2014 and October 29-30, 2014 public meetings and the October 15-16, 2014 workshop described above. The meetings will be held in EPA conference space at the Potomac Yard One Conference Facility on 2733 S. Crystal Drive, Arlington, VA 22202. EPA has established a website to facilitate registration by members of the public that wish to attend the meeting. This meetings shall include access by webinar and teleconference lines. Stakeholders and members of the public have been invited to request time on the agenda to make presentations as well as participate in an open dialogue on the meeting materials related to the IRIS chemicals on the Agenda. The amount of time allocated to each chemical will depend on the number of persons requesting time to make presentations and the extent of comments provided on each chemical. The Contractor shall provide assistance (including onsite assistance) to EPA prior to, during, and immediately after, the public meetings. Facilitation administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks)

1. Establish Communication Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA

WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

2. Support Provided Before the September 3-4, 2014, and October 29-30, 2014 Public Meetings and the October 15-16, 2014 Workshop.

- a. Making arrangements for the public to participate in the meeting through a teleconference line and webinar.
- b. Coordinating with Potomac Yard Conference Center AV and IT support to ensure adequate telephone and internet connections will be available at meeting location and ensuring AV equipment is available and setup before the public meeting.
- c. Making copies of the meeting agenda, and other meeting materials for distribution on the meeting dates.
- d. For the October 15-16, 2014 workshop only, identify and contact federal and non-federal experts with a broad based knowledge and expertise in the specific concepts of systematic review covered in the 2014 NRC report on the IRIS program including: 1) refining systematic review methodology, including methods to evaluate risk of bias, 2) advancing methodology to systematically evaluate and integrate evidence stream, and 3) combining quantitative results from multiple studies, presenting appropriate quantitative toxicity information, and advancing analyses and communication of uncertainty, with the goal of recruiting approximately 15-20 experts to participate in the workshop. Experts with an understanding of chemical hazard assessment are preferred. Potential invitees shall be asked to submit a bio-sketch for assessing their qualifications and must be approved by the WAM.
- e. For the October 15-16, 2014 workshop only, the Contractor shall arrange appropriate compensation (e.g., honoraria) for the time and effort of these non-federal experts. The Contractor shall arrange and provide for transportation, lodging, and logistical support for experts asked to participate in panel discussions (up to 3-5 experts for each area, total of approximately 10-15 experts) which will be held on site in Arlington, VA. The recruited experts not serving in panel discussions or unable to travel shall participate by webinar.
- f. Establishing a registration website, monitoring the registration website and compiling and maintaining the meeting registration list and presentation materials submitted by the public. Providing updated registration lists to EPA on a weekly basis after registration opens and more frequently when registration deadlines are approaching.
- g. Providing EPA security a list of attendees the day before the meeting.
- h. Managing the collection of public comments and presentations and preparation of electronic files needed during the public meeting. Loading all public and EPA presentations on the computer to be used during public meeting.
- i. Making arrangements for sign-in table and meeting agenda distribution on day of the meeting.

j. Conduct up to two dry-runs prior to each public meeting *and workshop* for the webinar and physical room set-up including operation of all AV equipment, internet connections, and computer presentations to be used in the meetings. May include set-up of cameras, sound equipment, computer locations in room, and webinar room.

3. Support Provide During the Meetings

- a. Staffing sign-in table, distributing meeting Agenda on meeting days.
- b. Providing name tents for key EPA personnel participating in the meeting.
- c. Webinar support including, but not limited to:
 - 1) Addressing technical difficulties raised by webinar participants.
 - 2) Organizing the presentation transitions between speakers.
 - 3) Monitoring and handling questions/comments from online participants and *reading* g those questions at the public meeting.
 - 4) Handling any audio/video issues or needs provided for online participants, including webcam video feeds.
- d. Establish teleconference line connection approximately 30 minutes before meetings start.
- e. Provide on-site meeting facilitation to promote adherence to schedule, a balanced opportunity for public participation from those attending within the room, and via webinar and teleconference line and a full dialogue of the scientific issues on the agenda. Contractor will report webinar questions to the meeting attendees in the room and on the conference line.

4. Support After the Meetings

- a. Provide final registration and attendees lists, both EPA and non-EPA.
- b. Provide notes, statistics, questions and poll results from webinar.

IV. SCHEDULE OF DELIVERABLES (for each meeting unless specified otherwise)

Deliverable	Due Dates
Teleconference NTE 1 hr - outlining how all tasks (listed	Within 3 days of award
above) shall be performed.	
For the October 15-16, 2014 Workshop only - Submit list	60 days before the workshop
of available experts to participate in the workshop to the	•
EPA WAM	
For the October 15-16, 2014 Workshop only - submit	45 days before the workshop
final list of experts to participate in the workshop to the	,
EPA WAM	
For the October 15-16, 2014 Workshop only - Complete	30 days before the workshop
arrangements for lodging, transportation, and other	
logistical support for experts attending workshop	· .

Submit electronic copies of registration list and presentations submitted by the public to EPA WAM	At least weekly and more often within 2 weeks of each meeting and the workshop
Schedule Teleconference Lines	4 days before each meeting and the workshop
Conduct up to two dry runs at Potomac Yard One, Arlington VA.	Within 2-4 weeks before each meeting and the workshop
Webinar support, meeting facilitation, sign-in table, teleconference lines	During the duration of each of the meetings and the workshop
Submit final list of registered attendees to EPA security for Potomac Yard One	2 days before each meeting and the workshop
Provide registration/attendance list and webinar statistics and info to WAM	Within 1 week after each meeting

V. SPECIAL CONDITIONS AND ASSUMPTIONS

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The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VI. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM): Amanda Boone-Edwards 703-347-8654 boone-edwards.amanda@epa.gov

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PERFORMANCE WORK STATEMENT Contract No. EP-C-14-001

WA 0-03 - Amend 5

Title: IRIS Public Stakeholder Meeting – Literature Searches, Evidence Tables, Exposure Response Arrays,

and Draft Assessments

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE:

CO award - October 31, 2014

BACKGROUND

NCEA will conduct a public meeting on Dec 15-16, 2014 that would occur during the next period of performance on the ICF contract. However, certain pre-meeting activities must begin before the next period of performance begins on Nov 1, 2014. I'd like to modify the current PWS to allow ICF to begin work on the following tasks for the Dec 15-16, 2014 public meeting.

This work must begin no later than Oct 10, 2014 and continue until Oct 31, 2014, after which a modified PWS should be in effect to continue these tasks, and other tasks, at the beginning of the next period of performance on Nov 1, 2014

1. Support Provided Before the December 15-16, 2014 Public Meeting.

- a. Establishing a registration website, monitoring the registration website and compile and maintain the meeting registration list and presentation materials submitted by the public. Providing updated registration lists to EPA on a weekly basis after registration opens and more frequently when registration deadlines are approaching.
- b. Managing the collection *of public comments and* presentations and preparation of electronic files needed during the public meeting. Prepare for loading all public and EPA presentations on the computer to be used during public meeting.
- c. In consultation with EPA, respond to questions from stakeholders and the public regarding the meeting.

EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM): Amanda Boone-Edwards

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-04

TITLE: Technical Support for Revision of the Draft Bristol Bay Assessment

PERIOD of PERFORMANCE: CO approval through 10/31/2014

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) in revising the second external review draft of the Bristol Bay Assessment (BBA; full title of report is "An Assessment of Potential Mining Impacts on Salmon Ecosystems of Bristol Bay, Alaska").

II. BACKGROUND AND SCOPE

The EPA is revising the external review draft Bristol Bay Assessment, which assesses risks to fish and fish-mediated risks to wildlife and humans from potential large scale copper mining in the Bristol Bay watershed. This work plan is a continuation of work on this project dating back to February 12, 2012, with the most recent addendum to this work assignment (Amendment 5) submitted on February 8, 2013.

The purpose of the activities proposed in this WA is to provide assistance to EPA in responding to comments on the draft assessment; preparing and/or revising analyses related to the mine site water balance, fisheries, and mine site characteristics and failures; and producing the final assessment report.

III. TECHNICAL APPROACH

The Contractor shall provide technical support to NCEA within the level of effort (LOE) allotted under this work assignment. EPA will document work on the tasks such that the sources of all information, assumptions, methods, and analyses are briefly but clearly identified and described. EPA will document input data and provide calculations, as appropriate, to clarify methods used and analyses performed. EPA will not duplicate any work performed by the Contractor under other work assignments or agreements, including (but not limited to) other current work assignments under this contract.

This WA consists of the following tasks:

Task 1: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. As part of the work plan, the Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan and that shows assigned personnel by task. The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager that shall be submitted simultaneously with the Work Plan for approval. Under this task, the Contractor shall perform other necessary communication activities related to management of the WA. Participation in weekly technical team calls and other discussions scheduled by EPA will also occur in conjunction with the tasks below.

Task 2: GIS support

The Contractor shall finalize GIS-based calculations and map development for the BBA. Specific tasks shall include revision and finalization of all calculations and associated geospatial files related to update of the digital elevation model (DEM) used in the second draft assessment. Examples of such revisions may include (but may not be limited to): updating mine scenario footprints, cumulative plant and ancillary areas, and estimates of non acid generating area in TSF2 and TSF3 embankment dams; updating subbasin delineations; updating gradient barrier analysis along the transportation corridor; and updating broad-scale habitat suitability metrics. Any creation of new or revisions to existing geospatial information shall be supported with metadata to ensure tracking of methodology and original sourcing in keeping with Federal Geographic Data Committee guidelines.

Task 3: Additional analyses related to DEM revision

The Contractor shall assist with additional analyses and revisions resulting from the change in the DEM within the BBA. Specific tasks may include (but may not be limited to): update of water balance and water chemistry calculations; update of the pipeline failure analysis; evaluation of a flood peak analysis comparing modeled floods to actual floods; update of the TSF dam failure analysis; and evaluation of a TSF spillway release scenario.

The TSF dam failure analysis shall include a review of model runs comparing piping and overtopping failures across at least two failure times. These failure times shall be selected to focus on hydrologic impacts (e.g. hydrograph magnitude and duration), with modeling of sediment distribution contingent on consultation with EPA.

Task 4: Text development and revision

The Contractor shall assist with needed text development or revision in response to peer review and public comments, to provide needed textual or methodological clarification to outstanding issues within the current draft BBA. Examples of such text development may include (but may not be limited to): text discussing cyanide use in gold processing; text discussing the use of dry stack tailings at the proposed mine site; text discussing the use of process chemicals; and text (both methodological and explanatory) associated with TSF analyses outlined in Task 3.

Task 5: Response to peer review and public comments

The Contractor shall contribute to and assist with technical contributions to response to comments documents associated with previous drafts of the BBA. This shall include responses to both public and peer review comments on both the May 2012 and April 2013 BBA drafts. Responding to comments may include both textual and analytical (e.g., via research into supporting documentation/citations) support.

Task 6: Document production for the final Bristol Bay Assessment report

The Contractor shall contribute to editing final revisions of BBA chapters, revising or creating any needed graphics, figures, or maps and their associated captions (particularly those affected by changes under Tasks 2 and 3), and preparing the BBA for final "print-ready" release and printing.

Task 7: Document production for the stand-alone executive summary

The Contractor shall revise the May 2012 draft of the BBA stand-alone executive summary to reflect changes in the updated executive summary text, any photos and graphics used, and prepare the document for final "print-ready" release and printing.

IV. DELIVERABLES AND SCHEDULE

The Contractor shall submit written deliverables as outlined by task in Exhibit 1. These deliverables must be of high quality, written in a clear, concise style, and have a logical organization and presentation. The Contractor shall submit deliverables early if they are completed ahead of schedule. The schedule shown is based on our current understanding of the project schedule. All deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g. Excel spreadsheets, Word documents, ESRI-supported geospatial files). For all listed deliverables, "days" are calendar days. **Electronic copies of all final written deliverables must be submitted to the Project Officer.**

Exhibit 1
Proposed Deliverables Schedule

Task	Deliverable/Milestone	Anticipated Due Date (days after contract award)
Task 1 – QAPP	QAPP	15 days
Task 2 – GIS support	Final shapefiles and associated data	22 days
	Metadata completed	22 days
Task 3 – Additional analyses related to DEM revision	Final data analysis	22 days
Task 4 – Text development and revision	New and revised text contributions	28 days
Task 5 – Response to peer review and public comments	Responses to peer review comments	40 days
	Responses to public comments (May 2012 draft)	40 days
	Responses to public comments (April 2013 draft)	40 days
Task 6 – Document production for the final	Revised maps and figures	40 days
Bristol Bay Assessment report	Technically edited BBA chapters	40 days
	Final, formatted BBA .	50 days
Task 7 – Document production for the stand-alone executive summary	Revised draft ES	50 days
stand-atone executive summary	Final ES	60 days

V. <u>EPA CONTACT INFORMATION</u>

Work Assignment Manager (WAM)
Jason Todd, Ph.D.
U.S. EPA, Mail Code 8623 P
Washington, DC 20460
(703) 347-0314
todd.jason@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 01-04 Amendment 1

TITLE: Technical Support for the Bristol Bay Assessment

Specify Section & Paragraph SOW: A. Assessment Issues and Documents E. Risk Assessment Support - Meetings

PERIOD of PERFORMANCE: CO approval through 8/30/2014

This amendment adds the following tasks:

Task 8: Archiving support for the Bristol Bay Assessment

The Contractor shall assist with documenting and archiving the files used in the various drafts of the Bristol Bay Assessment. Specific tasks shall include (but may not be limited to): documentation of which data sources (e.g., spreadsheets) were used in the 1st external review draft, 2nd external review draft, and final Bristol Bay Assessment; annotation of data spreadsheets as needed to clarify how different values were calculated; and assistance with development of the EndNote database for all references cited in the final Bristol Bay Assessment.

Task 9: GIS support for follow-on work to the Bristol Bay Assessment

The Contractor shall assist with GIS-based calculations and map development for follow-on work to the Bristol Bay Assessment, particularly the proposed determination document focused on mining of the Pebble deposit in the Bristol Bay watershed (hereafter, the PD). Specific tasks shall include (but may not be limited to): GIS-based calculations of different stream length and wetland area categories in the South Fork Koktuli, North Fork Koktuli, and Upper Talarik Creek watersheds as needed; and development of GIS-based maps (incorporating the same formatting conventions used in the final Bristol Bay Assessment) as needed.

Task 10: Additional analyses and text development for follow-on work to the Bristol Bay Assessment

The Contractor shall assist with additional analyses and text development to address targeted topics in the draft and final PD. Specific tasks shall include (but may not be limited to): assistance with calculations of fish abundance estimates and review of calculations as needed; and development and review of text addressing specific topics in the PD.

Task 11: Document production for follow-on work to the Bristol Bay Assessment

The Contractor shall assist with document production for the final PD. Specific tasks shall

include (but may not be limited to): technical editing of the draft PD; formatting of the final PD; development and finalization of graphics for the PD; and cover design for the final PD.

Task 12: Response to comments for follow-on work to the Bristol Bay Assessment

The Contractor shall provide assistance as needed to evaluate and develop responses to comment material submitted throughout the PD process. Specific tasks shall include (but may not be limited to): review of comments submitted by affected parties following their receipt of the 15-day letter; and drafting responses to specific points raised in those comment documents.

SCHEDULE OF DELIVERABLES

<u>Deliverables</u>	<u>Due Dates</u>
8. Archiving support	Draft within 4 weeks of amendment
1000	Final within 8 weeks of amendment
9. GIS support	Draft within 2 weeks of amendment
	Final within 4 weeks of amendment
10. Additional analyses and text development	Draft within 2 weeks of amendment
	Final within 4 weeks of amendment
11. Document production	Draft within 3 weeks of amendment
	Final within 5 weeks of amendment
12. Response to comments	Draft within 4 weeks of amendment
	Final within 8 weeks of amendment

EPA CONTACT INFORMATION

Electronic copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)

Jason Todd, Ph.D. U.S. EPA Mail Code 8623 P Washington, DC 20460 (703) 347-0314 todd.jason@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-05

TITLE: Technical Support for Scientific Panel Internal Review Meetings

Section and Paragraph of Contract SOW: Section A.1.(c) Human Health Assessment Documents

PERIOD OF PERFORMANCE: CO issuance thru October 31, 2014

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Office of Research and Development (ORD), National Center for Environmental Assessment-Cincinnati (NCEA-C), in obtaining technical support services for the scientific panel internal review meetings. The Contractor shall provide professional note-taking services to support this effort.

II. BACKGROUND

NCEA supports the Superfund Program by developing provisional toxicity values (PTVs) such as reference doses, reference concentrations, and cancer values for chemicals where such information is not available in EPA's Integrated Risk Information System (IRIS). Provisional toxicity values are documented in Provisional Toxicity Value documents.

In order to streamline the PTV review process and ensure consistency, an internal scientific review panel was established by NCEA-C to review each chemical and resolve technical issues prior to the completion of an external peer review and the clearance process. The scientific internal review panel meets on a regular basis (once per month or as deemed necessary) for approximately 3 hours per meeting. The Panel consists of seven technical reviewers (EPA senior scientists) and one professional note-taker.

III. STATEMENT OF WORK

Task 1: Establish Communication - Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the EPA WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan and Staffing Plan - The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, showing assigned personnel by task and the qualifications of the proposed personnel.

Qualifications - The Contractor shall provide a qualified professional note-taker with a minimum of 8 years of experience in risk assessment, toxicological terminology, and related topics.

Specific Requirements - The Contractor is requested to begin work under this WA immediately upon receipt from the Contracting Officer, while simultaneously preparing a Work Plan.

- Task 3: Preparation for Panel Meeting The Contractor shall provide professional note-taker services to perform Tasks 3 7, for up to 10 Panel Meetings to be held during the period of performance of this WA. The professional note-taker services shall include preparing for each scientific review panel meeting by completing an overview of the designated PTV draft manuscripts and checklists to be reviewed during each meeting. During each Panel Meeting, a total of 1-3 chemicals will be discussed. Written information for each chemical typically ranges from 30-75 pages in length. Access to information for each chemical will be provided to the Contractor a minimum of five (5) business days in advance of each scheduled meeting by the EPA WAM. The Contractor shall obtain the required information through the Environmental Science Connector and/or the Health and Environmental Research Online (HERO) database.
- Task 4: Schedule for Panel Meetings The Contractor shall provide note-taker services via teleconference, or in person if deemed necessary and as agreed to by the EPA WAM on a case by case basis. All meetings will take place at the U.S. Environmental Protection Agency, Andrew W. Breidenbach Environmental Research Center, 26 W. Martin Luther King Drive, Cincinnati, OH, 45268. The meetings typically are held in the afternoon between noon and 5:00 pm. The meeting dates and times will be set by the EPA WAM at least 1 week in advance. The first Panel Meeting for this Performance Period will be determined by the EPA WAM. The Contractor will be notified by the EPA WAM of all scheduled meetings via written technical direction. Since the room locations are not known, if deemed necessary by the EPA WAM that the note-taker attend in person, the note-taker should call (513) 569-7596 upon entering the building on the days of the meetings for an escort.
- **Task 5:** Equipment and Services The Contractor shall furnish a laptop for the note-taker to use during the scientific review panel meetings. EPA will provide the necessary IT support including standard cables, and any other required connectors for laptop use.
- **Task 6: Draft Written Reports -** The Contractor shall provide a draft written report of the results of each scientific review panel meeting to the EPA WAM within 4 business days following the meeting. In response to the draft written report, the EPA WAM will provide any comments, changes, or questions to the Contractor within 5 business days after receipt.
- **Task 7: Final Written Reports -** Upon receipt of the EPA's response, the Contractor shall provide a final written report of the results of each scientific review panel meeting to the EPA WAM within 5 business days.

IV. ANTICIPATED DELIVERABLES

All written deliverables shall be provided in electronic format in Microsoft Word.

V. DELIVERABLES AND SCHEDULE

Task 1 – Establish Communication	Within 3 days of start of WA
Task 2 – Work Plan and Staffing Plan	Begin work immediately and simultaneously prepare Work Plan and Staffing Plan within 15 calendar days after receipt of WA
Task 3 – Preparation	Prepare for scientific review panel meetings within 5 days of each meeting
Task 4 – Panel Meetings	Furnish professional note-taker to attend up to 10 Panel Meetings, as scheduled by the EPA WAM
Task 5 – Equipment	Furnish laptop at each scheduled Panel Meeting
Task 6 – Draft Written Report	After each Panel Meeting, provide a draft written report to the EPA WAM within 4 business days
Task 7 – Final Written Report	Upon receipt of WAM's response to each draft written report, provide a final written report to the EPA WAM within 5 business days

All deliverables shall be submitted electronically as Microsoft Word documents. Electronic (pdf) copies of all deliverables shall be sent to the EPA Project Officer (PO) shown below.

VI. MANAGEMENT CONTROLS

1. The Contractor shall certify there is no conflict of interest. The Contractor shall provide the following conflict of interest certification in the Work Plan:

I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this WA exist. Personnel who perform work under this WA, or relating to the WA, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this WA have been reported to the EPA WAM or are attached, if applicable.

- 2. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
- 3. All deliverables shall be reviewed for conformance to the requirements of this WA before being approved as final.
- 4. The Contractor shall comply with other applicable requirements for final WA reports stipulated in the Agreement.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (a) Formulation of Agency policy
- (b) Selection of Agency priorities
- (c) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or Work Assignment, the contractor shall immediately contact the EPA WAM.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the WA, and shall provide a bi-weekly update to the EPA WAM by telephone as necessary, or in the form of a report submitted via email, for the duration of the WA. The Contractor shall be prepared to participate in additional conference calls or email exchanges, as necessary.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)

Teresa Shannon 513-569-7596 513-487-2542 (fax) shannon.teresa@epa.gov

Alternate Work Assignment Manager (Alt. WAM)

Scott Wesselkamper 513-569-7256 513-487-2542 (fax)

Email: wesselkamper.scott@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
National Center for Environmental Assessment
26 W. Martin Luther King Drive
MS-A110
Cincinnati, OH 45268

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PERFORMANCE WORK STATEMENT

Contract Number: EP-C-14-001 Work Assignment Number 0-06

Title: Risk Assessment Forum Dose Response Assessment State of the Science Reviews

SOW Section & Paragraph: A. Assessment Issues and Documents, G. Literature Search

PERIOD OF PERFORMANCE:

Award – October 31, 2014

A. BACKGROUND

The National Research Council (NRC) report *Science and Decisions* (2009) recommended the Environmental Protection Agency (EPA) develop a phased-in approach to implementing a unified dose-response assessment methodology for cancer and noncancer endpoints, incorporating a systematic evaluation of background exposures and disease processes, possible vulnerable populations, and modes of action that may affect human dose-response relationships. The report also recommended that reference dose/reference concentration (RfD/RfC) should be redefined to take into account the probability of harm. The participants of the EPA Risk Assessment Forum (RAF) Human Health Risk Assessment Colloquium (October 2010) explored the recommendations and proposed the development of a series of State of the Science (SoS) review papers as an intermediate step in the development a comprehensive plan to address dose-response recommendations in *Science and Decisions*.

B. PURPOSE

This assignment directs the Contractor to develop a comprehensive, systematic review and first level synthesis of the literature in support of the SoS Reviews on the following critical topics in Dose-Response Assessment as scoped by the EPA Risk Assessment Forum Dose Response Technical Panel:

- 1. Methods/approaches and data for quantitatively estimating variability in human biological responses from exposure to chemicals; and
- 2. Methods/approaches for quantitatively estimating human health risk from exposure to chemicals by extrapolating from *in vivo*, *in vitro*, and epidemiological data.

For both systematic reviews, methods related to variability in exposure or exposure assessment will not be addressed.

This work assignment (WA) will serve as a general description of WA tasks. Technical direction will be given to provide additional technical detail as more info is known.

C. KNOWLEDGE AND SKILLS REQUIRED

The Contractor shall provide technical support in collecting and entering data in spreadsheets, organizing information, and summarizing, evaluating and synthesizing literature related to the topics described above.

These tasks require expertise in multiple disciplines such as epidemiology, toxicology, pharmacology, physiology, pathology, microbiology, public health, decision analysis, quantitative dose-response assessment, quantitative uncertainty analysis, human health economics, biostatistics, chemistry, and mathematical modeling, including Benchmark Dose (BMD) modeling, physiologically-based pharmacokinetic (PBPK) modeling, and computational toxicology modeling.

The tasks also require expert personnel having the knowledge and ability to conduct a thorough search of the literature and to fully and critically evaluate study methodologies and results in the technical disciplines identified above. Analyses must be scientifically sound and sufficiently documented.

D. TASKS

Task 1: Establish Communication Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall prepare a written work plan describing how the tasks in this PWS will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates

Task 2: Prepare Quality Assurance Project Plan

The contractor shall develop a quality assurance statement for this work assignment for the EPA Work Assignment Manager's (WAM) approval. The workplan and quality assurance project plan (QAPP) shall be submitted simultaneously for the WAM's approval. The contractor shall not perform any work under this work assignment until the quality assurance project plan is reviewed and approved by the WAM.

Task 3. Literature Search

The Contractor shall conduct extensive and exhaustive searches of all relevant databases on toxicological, epidemiological, health, or economic-specific literature. The Contractor shall conduct literature searches for key studies, retrieve pertinent articles, and provide data extraction spreadsheets. A specific plan for the search and retrieval of the relevant information and details of the search strategy shall be developed. Results of literature searches shall identify relevant scientific information and likewise exclude information that is not relevant to the task. The Contractor shall implement procedures to efficiently screen out studies that may, for example, have key words in common with search criteria, but which do not provide information on search subject goals. Detailed records shall be kept as to the databases, keywords used for electronic searches, procedures for identifying additional literature, and screening of studies so that the search could be reproduced/revisited/updated if necessary. During examination of the identified literature, the Contractor shall place primary emphasis upon the adequacy of study design, quality control, and interpretation of results of each study, and determine the article's relevance to the topics described above. Primary literature sources shall be used exclusively, except in rare, extenuating circumstances.

The following type of literature shall be systematically identified and reviewed for Topic 1 described above:

- Primary data on variability in human responses with respect to internal dose, biological response, or adverse health outcomes. Such data may include:
 - Observational human data (e.g., epidemiology)
 - o Experimental human data (e.g., clinical studies of pharmaceuticals)
 - o Experimental animal data (e.g., genetically diverse mouse models)
 - o Experimental in vitro data (e.g., genetically diverse human cell lines)
- Methods/approaches for quantitatively estimating human variability and its uncertainty with respect to response to a specific environmental chemical. This would include *in silico* approaches such as population PK modeling (e.g., SimCYP).
- Methods/approaches for estimating the distribution of human variability across chemicals. This would include approaches such as those developed by Hattis and colleagues (Hattis, D., Baird, S., and Goble, R. 2002. A straw man proposal for a quantitative definition of the RfD, Drug Chem Toxicol. Nov; 25(4): 403-36) based on historical data.

The following type of literature shall be systematically identified and reviewed for Topic 2, described above:

- Methods/approaches for quantitatively estimating the population incidence of an adverse health outcome as a function of exposure, based on in vivo, in vitro, and/or epidemiologic data.
- Methods/approaches for quantitatively estimating the change in population distribution of a biological measurement as a function of exposure, based on in vivo, in vitro, and/or epidemiologic data.
- Applications of such methods/approaches to a specific chemical and adverse health outcome or biological measurement.

Task 4. Data Extraction

For articles with primary data, the following shall be extracted into a database or spreadsheet:

- The original data, to the extent reasonably feasible;
- Characteristics of the population from whom the data were obtained (e.g., species/strain, age/lifestage, sex, etc.); and
- The degree to which the population being studied includes different sources of variability (e.g., genetics; epigenetics, gender, lifestage, existing health conditions, co-exposures, nutrition, psychosocial stressors).

For articles with either primary data and/or methods/approaches, the following meta-data shall be extracted into a database or spreadsheet:

- The "independent" variable, such as a measure of exposure (e.g., media concentration, ingested dose, blood concentration, etc.)
- The "dependent" variable(s), such as a measure of response for which variability is being estimated (e.g., enzyme activity, blood or tissue concentration, clinical measurement, disease diagnosis, etc.);
- Any measured covariates such as age, BMI, etc
- Any extrapolations applied; and

• Any mathematical assumptions for quantifying variability (e.g., lognormal distribution, continuous or discrete distributions, single- or multi-modal distributions, combined distributions such as independence, etc).

All extracted data and meta-data should be consistent with QA/QC procedures to ensure accuracy.

Task 5. Technical Editing

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction (see attachment entitled "Technical Direction"). The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

Task 6. Delivery of the Final Product

The Contractor shall deliver three (3) hard copies in addition to the electronic version (MS Office 2007 unless otherwise stipulated) of the edited document to the COR including both clean and marked drafts. The latter shall be a revised document presented as a "track changes".

E. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Conference Call.	In accordance with contract
Task 2. QA Plan	In accordance with the contract
Task 3. Shall conduct extensive and exhaustive searches of all relevant databases on toxicological, epidemiological, health, and economic-specific literature.	As specified in the Technical Direction.
Task 4. Shall extract requested data and meta-data into a spreadsheet or database.	As specified in the Technical Direction.
Task 5. Shall review and edit assigned text per technical direction, including quality control for grammatical, syntax, and spelling errors.	As specified in the technical direction.
Task 6. Shall deliver three (3) hard copies and one (1) electronic version (MS Word 2007) of the draft document to the COR including each in both clean and marked drafts. The latter shall be a revised document presented as a "track changes".	As specified in the technical direction.

F. ACCEPTANCE CRITERIA

Final products shall be produced by the Contractor upon the EPA WA COR's approval through written, technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Office 2007, Powerpoint 2007, and Excel 2007 computer format unless otherwise stipulated.

G. MANAGEMENT CONTROLS

Periodic meetings between the EPA and the Contractor WA managers are encouraged to discuss any questions

that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this WA. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this WA. The interaction will be technical communication via technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

Work Assignment COR:

Julie Fitzpatrick
Office of Science Advisor
U.S. EPA (8105-R)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-4212
Fax: (202) 564-2070

Alternate Work Assignment COR:

Lawrence Martin
Office of the Science Advisor
U.S. EPA (8105-R)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-6497
Fax: (202) 564-2070

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Project Officer Name Melissa Revel	v-Wilson	(Date)		FAX Number: Branch/Mail Code:				
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Project Officer Name Melissa Revely-Wilson Branch/Mail Code:										
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-07

TITLE: Dose-response and Quantitative Analysis (SWG support for IRIS)

Principal Section & Paragraph of SOW: A.1 and B.1,2,5

PERIOD OF PERFORMANCE: CO Approval – November 1, 2014

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide dose-response analyses, statistical analyses, and other quantitative analyses and research as identified in the contract performance work statement, Sections A(1) and B(1,2, and 5). Data entry and data QA, and data management will be a part of these tasks. Reporting of results in tables of standard IRIS formats will be a part of these tasks. The majority of work is expected to consist of dose-response analyses and data analysis supporting development of "evidence tables."

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this Work Assignment

This WA supports continued development and modification of software tools (DRAGON, WIZARD, and the dosimetry tool, and exposure-response array) that are based on Microsoft Access, Microsoft Excel, and associated Visual Basic for Applications code.

The contractor shall provide personnel who are proficient with the software tools DRAGON, WIZARD, Microsoft Access, Microsoft Excel, and knowledgeable regarding dosimetric conversions BMDS (Benchmark Dose Software; at http://www.epa.gov/ncea/bmds) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (*.(d),*.dax, *.ssn, *.opt).

Under this WA, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (enumerated below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager.

Agency guidance will be applied and exceptions to such guidance will be clearly noted. Agency guidance should be used: (a) to determine the suitability of studies and data used; (b) to guide the preparation of data and the adjustment of doses or concentrations for intermittent and time-varying exposures and less-than-lifetime exposures; (c) to guide the conduct of dose-response modeling and model selection; (d) to guide the development of RfC/RfD values, cancer slope factors, and all other subject matter included in Chapters 5 and 6 of a Toxicological Review.

The work shall be conducted so as to be consistent with EPA's *Benchmark Dose Technical Guidance Document* and other relevant EPA guidelines (e.g., guidelines for carcinogen risk assessment, neurotoxicity, reproductive toxicity, developmental toxicity, and inhalation dosimetry (see documents at http://www.epa.gov/iris/backgrd.html). Quantitative dose-response analyses shall be conducted and reported according to the *Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS*, to be provided by EPA. If any exceptions to the foregoing guidance and checklist are required for an analysis, they should be noted and explained.

Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]). The contractor shall use the most recent issue of BMDS (BMDS 2.x) for dose-response analyses, where this is feasible and efficient; otherwise, the contractor shall use the latest versions of BMDS executable 'modules' (e.g., multistage.exe) if the latest GUI is not used [these modules are installed with BMDS 2.x].

Input data and BMDS accessory files developed under this Task for the various dose-response analyses shall be delivered. This includes spreadsheets, input files to the BMDS Wizard, and accessory files used and produced by BMDS (e.g., BMDS related files: *.(d), *.set, *.dax, *.opt, *.ssn, *.out, *.002, *.plt, *.emf, and Excel export files from BMDS2). These materials will be organized in subdirectories or by file names so as to distinguish cancer and noncancer effects, exposure routes (inhalation, diet, drinking water), and continuous vs.

dichotomous (quantal) responses. These files shall be named or described (e.g. in a Read_Me.txt file or other document) or otherwise organized sufficiently that the data sets and endpoints are recognizable. These materials will be transmitted in electronic form, e.g., by email in a ZIP file or delivered physically on a CDROM.

The contactor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM (Work Assignment Manager) or EPA Project Officer.

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment.

The contractor shall develop a quality assurance project plan (QAPP) for this project. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

Deliverables: QAPP

Due Date: 15 days after issuance of this Work Assignment

Task 2. Data Entry and Data QA

Following approval of the workplan and QAPP, the contractor shall review the data sources to identify data for each endpoint, enter the data into an electronic medium (if not already provided in this form), and verify the data. All data shall be verified as correctly entered from the source. Source publications will usually be accessed using EPA's HERO database.

The contactor is not responsible for verifying secondary data quality for studies and endpoints identified by the EPA WAM <u>unless</u> required to do so in the written Technical Direction pertaining to a specific request.

The contactor will provide, to the EPA WAM, spreadsheets that indicate the source of the individual data element from a study by reference to the page, table, figure, footnote, etc., from the original report being cited. Data will be entered in the units provided in the original paper, with any necessary transformations explicitly performed in the spreadsheet. Units conversions and adjustments for intermittent or non-constant exposure shall be documented explicitly for each data set, with comments as needed. Possible cases of systematic differences in survival between dose groups (typically, lower survival in high dose groups) will be 'flagged'.

When a request involves multiple studies, data will be assembled and organized in either the BMDS WIZARD or in DRAGON, unless the contractor and the EPA WAM agree not to do so.

Deliverables: Notification of completion to EPA WAM by email or telephone. As necessary, questions and

problems regarding data will be delivered, with proposed methods of resolution.

Data will be delivered after task 2 completion only if specifically requested (usually the data will

be delivered with results of benchmark dose analyses under the Tasks that follow this one).

Due Dates: To be specified either in written technical direction after consultation with the contractor; or, if

not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12

distinct endpoints, or (c) one working day for every 8 distinct studies.

Task 3: Non-Cancer Data Analysis and Benchmark Dose Modeling

Under this task, the contractor will evaluate non-cancer data sets for dose-response modeling in a manner consistent with EPA's Benchmark Dose Technical Guidance Document and Annotated Checklist of Best Practices for Dose-Response Analyses for IRIS. The contractor will consult with the EPA WAM as to potential problems with particular experiments and data sets. Prior to modeling data, the contractor will perform any necessary dosimetric adjustments and/or conversions, select appropriate benchmark responses (BMRs) for each endpoint, identify important or unusual statistical issues, and flag data not amenable to benchmark dose modeling. Additionally, the contractor will perform data verification and documentation as outlined in Task 2 prior to dose-response modeling.

To facilitate comparison of multiple candidate PODs, summary results for BMDs, BMDLs, NOAELs and LOAELs will be reported in terms of Human-Equivalent Dose or Concentration (HED/HEC). For chronic and subchronic oral (ingestion) exposures (specifically excluding developmental and short-term studies), a BW^{3/4} default animal-human conversion be made. Reporting units will be mg/kg-day for oral exposure and either ppm or mg/m³ for inhalation exposure. RfDs will be reported in mg/kg-day and RfCs will be reported in mg/m³.

The contractor will model data amenable to benchmark dose modeling using EPA's BMDS2.x. Results will be summarized in tables that report key statistics for model goodness of fit (AIC, p-value for goodness of fit, degrees of freedom for the Chi-square test, and largest scaled Chi-square residual). Based on these results along with considerations of biological relevance, the contractor will identify candidate data sets, endpoints, and models that could be used as a basis for a POD for both ingestion and inhalation exposure routes, as the data permit. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with

recommended models; summary tables showing key results for selected

models for the various datasets (endpoints) by exposure route

Due Date: 7 calendar days after: completion of data entry and QA, and resolution of any

questions or issues referred to the EPA WAM regarding the data Revisions – dates to be specified in written technical direction

Task 4: Cancer data analysis and dose-response modeling .

Under this task, the contractor will review the study reports identified by the EPA WAM to identify data sets on cancer incidence amenable to analysis of individual tumor sites. For both ingestion and inhalation

exposure routes, as the data permit, cancer data amenable to benchmark dose modeling will be prepared and verified as outlined in Task 2.

The contractor will also identify studies amenable to modeling risk from multiple tumors per animal (when data exists for multiple tumor sites in one study for one sex of one rodent strain, EPA may request an analysis of risk from multiple tumors using the MS COMBO program or using the "multi-tumor" option of BMDS).

Individual tumor data will be fitted using the 'multistage cancer model' of BMDS (with coefficients constrained to be non-negative). Multistage model order selection will be based upon a minimum AIC criterion unless otherwise specified in writing.

After conducting BMDS modeling, the contractor will identify those data sets, endpoints, and models (i.e., orders of the multistage model) that could be used as a basis for unit risk/cancer slope factor. If so directed in writing, the contractor will summarize results in tables in an MS/Word document(s); tables and footnotes will be modeled after current IRIS table templates.

Deliverable: spreadsheets holding input data; output (analysis) results by data set with

recommended models; summary tables showing key results for selected

models for the various datasets (endpoints) by exposure route

Due Date: 7 calendar days after: completion of data entry and OA, and resolution of any

> questions or issues referred to the EPA WAM regarding the data Revisions – dates to be specified in written technical direction

Task 5: Time to Tumor Analysis

The contractor may be requested to review cancer bioassay studies (provided by the EPA WAM) to identify and propose those for which time to tumor analysis may need to be applied, or such studies may be identified by the EPA WAM. Time-to-tumor analysis would need to be applied if survival differs substantially among the dose groups.

The contractor will use the "MSW" program for time-to-tumor analysis and will report any failures of the MSW program to solve the BMDL. If this occurs, the program "ToxRisk" (version 5.3) will be used to obtain a BMDL. Subsequently, parameter estimates and BMD resulting from MSW and ToxRisk will be compared to determine similarity. The contractor will also call attention to any instances of parameter estimates on a boundary. Where higher-order coefficients are nonzero, estimates will be presented for all model orders between 1 and the number of dose groups less 1. The EPA WAM may request a conventional BMDS cancermodel analysis based on poly-3 weights applied to the individual animal data, as an alternative to time-to-tumor modeling.

Deliverables: input and output files used/produced by software to fulfill this task (text files

and/or spreadsheets); a report with tables summarizing the data, data sources, and results, suitable for inclusion in an Appendix to a Toxicological Review

Due Date: to be specified in written technical direction. EPA will not require completion of more than 6

data sets per work day (to include data entry and QA, data analysis, and reporting) except by

prior agreement with the contractor

Task 6: Prepare Draft Materials for IRIS Toxicological Reviews

The contractor, when requested in a technical directive, shall prepare draft portions of an IRIS Toxicological Review, relevant to dose-response or quantitative analyses conducted under other tasks herein, and following the style of the IRIS template for Toxicological Reviews (to be provided by EPA). Drafts may include Evidence Tables, Study Summaries, exposure-response arrays, dose-response modeling, selection of an oral reference dose (RfD), inhalation reference concentration (RfC), cancer modeling (including derivation of a cancer slope factor and inhalation unit risk), Chapter 2 text and tables, Appendix materials, and related narratives.

Deliverables and Due Dates:

Drafts with supporting materials, date to specified in written technical direction.

Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.

Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

Task 7. Study and Endpoint Screening and Selection for Hazard ID and Dose-Response Analysis

This task may require:

- review of studies for adequacy to support inferences about toxicity and carcinogenicity, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- review of studies to support dose-response analysis, using decision criteria either provided by EPA or proposed by the contractor and confirmed by EPA
- preparation of "evidence tables" in the current IRIS format
- other tabulations of studies using a layout provided by EPA or proposed by the contractor and confirmed by EPA, and computations needed to calculate results for such tabulations
- graphical presentations comparing studies and endpoints quantitatively and qualitatively, including but
 not limited to exposure-response arrays and forest plots, and computations needed to calculate results for
 such plots

If so requested, the contractor will document in such tables the preliminary decisions (including rationales) about critical endpoints, to include (of so directed) MOA, sensitive populations, and candidate/principal studies for hazard evaluation and RfV derivation.

If so requested, the contractor will document the details that support preliminary decisions regarding potential critical endpoints, MOA, sensitive populations, and candidate/principal studies.

The EPA WAM will communicate detailed requirements by Technical Directions when this Task is undertaken, and will provide examples from recent Assessment documents.

Deliverables: Spreadsheet worksheets and Word tables; supporting narrative and appendices when requested

Due Dates:

Drafts with supporting materials, date to specified in written technical direction.

Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses.

Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task	Schedule (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this WA
2. Data Entry and QA	To be specified in written technical direction. If not so specified, then the greater of: (a) 2 working days or (b) one working day for every 12 distinct endpoints, or (c) one working day for every 8 distinct studies.
3. Non-Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
4. Cancer Modeling	To be specified in written technical direction. If not so specified, then 7 calendar days after: completion of data entry and QA, and resolution of any questions or issues referred to the EPA WAM regarding the data
5. Time-to-Tumor Modeling	To be specified in written technical direction. EPA will not require completion of more than 6 data sets per work day (to include data entry and QA, data analysis, and reporting) except by prior agreement with the contractor
6. Draft Materials for IRIS Tox. Reviews	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt of comments and written technical direction from EPA
7. Study and Endpoint Screening	Drafts with supporting materials, date to specified in written technical direction. Input data sets and results (output), and supporting results & documentation, three weeks after completion of dose-response analyses. Due dates for revisions may be specified in written technical direction; if not so specified, then within 10 working days of receipt

of comments and written technical direction from EPA

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)

John Fox

703-347-8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

Mailing Address:

U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P) 1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:

U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

EPA Alternate Work Assignment Manager (Alt-WAM)

Christine Cai, 703-347-8517 (voice), 703-347-8689 (fax), email cai.christine@epa.gov

(same as for WAM)

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-08

TITLE: Software Tools to Support IRIS Data Management, Analysis and Reporting

Principal Section & Paragraph of SOW: C. Risk Assessment Data Bases and Computer Tools

PERIOD OF PERFORMANCE: CO Approval - October 31, 2014

I. PURPOSE

The purpose of this Performance Work Statement (PWS) is to provide services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide software tools and templates to support data management and quality assurance, summarization and analysis of data (e.g., for hazard evaluation and dose-response modeling) and the organization and reporting of these data and analyses, primarily for the preparation of toxicological reviews by NCEA's IRIS program.

II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. When supported by available data, the database provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. Government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

Under a previous contract, software utilities (DRAGON and BMDS-WIZARD) were developed for IRIS. These tools are based on Microsoft Access, MS/Excel, some VBA code, and BMDS software. The purpose of these tools is to expedite the entry and QA of information and data from toxicological studies, to expedite the production of tables for IRIS chemical assessments, and to expedite the conduct of dose-response analysis and related calculations and the review and reporting of results. These tools have greatly increased throughout and decreased effort for assembling and reporting information for IRIS assessments.

III. SCOPE OF WORK: TASKS AND DELIVERABLES

Requirements Specific to this PWS

This PWS supports continued development and modification of software tools (DRAGON, WIZARD, and the dosimetry tool, and exposure-response array) that are based on Microsoft Access, Microsoft Excel, and associated Visual Basic for Applications code. Therefore, the contractor shall provide personnel who are already expert in the areas of (a) QA and revision control for program codes, (b) Visual Basic for Applications programming, (c) applications based on commercial spreadsheets (specifically, Microsoft Excel) and (d) commercial database management systems (specifically, Microsoft Access).

BMDS (Benchmark Dose Software; at http://www.epa.gov/ncea/bmds) is the primary software tool used by IRIS for dose-response modeling, and it is used by DRAGON and WIZARD to conduct dose-response modeling. Therefore, the contractor shall provide personnel who are already experienced with benchmark dose modeling, the use of BMDS, and the formats of BMDS auxiliary files (*.(d),*.dax, *.ssn, *.opt).

Task 1: Quality Assurance Project Plan (QAPP)

The contractor shall prepare Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment.

The contractor shall develop a quality assurance project plan (QAPP) for this project. The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager and NCEA's QA official.

Deliverables: QAPP

Due Date: 15 days after issuance of this Performance Work Statement (PWS).

Task 2. MS/Word templates

<u>Background</u>: "Streamlining" (revising the content and format) of IRIS toxicological reviews is an ongoing process which will be informed by feedback from the National Academy of Sciences, reviewers, and stakeholders. From time to time, EPA may require new or revised MS-Word templates (associated with BMDS Wizard and Dragon) as IRIS revises its formatting of toxicological reviews. EPA may also require changes or additions to the data-management, calculation and reporting capabilities of Wizard and Dragon to support changes in data calculations and changes in reporting for toxicological reviews.

The contractor will create or revise (as appropriate) MS/Word templates and styles used to create tables for use in IRIS toxicological reviews. These include (but are not limited to) Study Summary tables, tables summarizing modeling results, and Evidence Tables.

EPA expects to request one revision to each template currently in use, and development of two new templates.

Deliverables: revised MS-Word templates

Due Dates: to be specified in written technical direction

Task 3. DRAGON (Dose Response Analytical Generator and Organizational Network)

EPA expects to request additions of new data fields and simple calculations in Dragon, to support reporting needs for evidence tables. For the purpose of estimating cost for this Work Assignment, the contractor should assume that a dozen such changes may be requested by EPA. Changes or additions to data fields for developmental studies can be expected. Data forms or fields for neuro-developmental or neuro-toxicological studies will be added.

Examples of such data fields and calculations added in the past included: indicators for significance-test results from original publication, comparing treatments to control (P-values and NA when not available); calculation of 'percent change' from control for continuous responses; calculation of empirical extra-risk for treated groups for dichotomous data.

Export and import capabilities (e.g. for data exchange with Meta-data Viewer, Graphpad, and Excel) may be requested. Forms, or export capabilities, or reporting formats compatible with HERO may be requested.

The contractor will verify correct operation of DRAGON during development and after completion of a beta version, and will report periodically to the WAM on results of testing and on measures to correct any problems found by testing or in use.

This work assignment will continue and extend development of DRAGON but shall not duplicate work already done for the federal government. [For example, modifications to DRAGON made under another work assignment would not be repeated under this work assignment.]

Deliverables and due dates:

New and revised fields and forms will be specified in written technical direction Drafts of DRAGON for review - arranged by consultation with WAM Reports on testing with 'practice data' - approx. every 4 weeks during development Wizard modeling templates - to be requested in written technical directions Word report/table templates - to be requested in written technical directions

Task 4. User Manuals and Tutorials

User manuals will be developed for DRAGON and WIZARD (these will also cover use of the imbedded dosimetry tool). Scope: the manuals will provide users with instructions for use, but are not expected to explain the workings of Access or Excel or the details of the associated VBA code. Manuals will be provided with databases that may be used in the manuals as examples and can be used by users as templates. Necessary information will be provided separately on any modifications (including VBA code) and configuration steps needed to use these databases on a proxy server. Manuals will be revised within one month of any significant changes to DRAGON or WIZARD.

Tutorials will be provided (dates to be determined in consultation with EPA). These may take the form of demonstration/lectures, either on-site at EPA locations or as webinars. Provision will be made for user questions and answers. For the purpose of cost estimating for this work assignment, the contractor should assume that EPA would request eight demonstration/lectures, four at each of two EPA locations. Some might be conducted via webinar, but others might be in-person at different EPA locations. These tutorials may cover different modules separately (e.g., Animal module, Epidemiology module) and may emphasize different forms (e.g., developmental data) for different IRIS workgroups.

Deliverables and due dates:

Manuals: draft within 15 working days of approval of this task; revised drafts within 10 working days after EPA returns comments

Tutorials: dates to be arranged in consultation with EPA

Task 5. User Group Meetings

Meetings will be arranged as telephone conferences and/or web conferences. The contractor shall coordinate and organize meetings, distribute agendas, and report minutes and action items.

Meeting frequency will be determined by consultation with EPA; expected frequency is monthly to bimonthly, but ad-hoc meetings may be called (as needed) to discuss new modules and new or changed features. Meetings may be arranged separately for different user groups, for example, users of epi-DRAGON and users of Animal-DRAGON. Details of attendees and subject matter will be arranged in consultation with EPA. The principal purposes are (a) to gather input from users regarding DRAGON features and usability (existing or planned) and (b) to share information about and reconcile needs of different users both within EPA (including HERO users and staff) and in other federal agencies.

<u>Deadlines</u>: meeting dates and times to be determined in consultation with EPA and other users

Task 6. BMDS WIZARD

The BMDS WIZARD will be updated to accommodate changes to BMDS as these occur and if BMDS changes require modifications to the WIZARD. The contractor should notify the WAM when a need is determined; work will then be initiated after receipt of written technical direction from EPA

Deliverables: revised BMDS WIZARD

Deadlines: to be specified in written technical direction

V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be changed using written Technical Direction.

Task .	Schedule (*all days are elapsed calendar days unless otherwise stated)
1. Quality Assurance Project Plan	15 days* after receipt of this PWS
2. MS/Word templates	to be specified in written technical direction
3. DRAGON	Drafts of DRAGON for review: arranged by consultation with WAM Developmental forms: mid-December 2013
ч	Oral reports on testing with practice data or in use for EPA projects – approx. every 4 weeks during development
	Beta versions of DRAGON after adding new modules - arranged by consultation with WAM
	Revisions in response to EPA comments - 14 work days after receiving technical direction
4. User Manuals and Tutorials	Manuals: draft within 15 working days of approval of this task. Revised drafts within 10 working days after EPA returns comments.
	Tutorials: dates to be arranged in consultation with EPA
5. User Group Meetings	to be determined in consultation with EPA and other users
6. BMDS WIZARD	to be specified in written technical direction

VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM)

John Fox

703-347-8598 (voice), 703-347-8690 (fax), email Fox.John@epa.gov

Mailing Address:

U.S. EPA, ORD/NCEA-Washington (Mail Code 8601 P) 1200 Pennsylvania Ave, NW, Washington, D.C. 20460

Courier Deliveries:

U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment Two Potomac Yard North, 7th Floor N-7954, 2733 S. Crystal Drive, Arlington, VA 22202

EPA Alternate Work Assignment Manager (Alt-WAM)

Krista Christensen, 703-347-0185 (voice), email Christensen.Krista@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-09

TITLE: Summary of Monitoring and Long-Term Observing Network Capabilities to Detect Global Change Impacts in Ecosystems

Specify Section & Paragraph SOW: Please select from the following:

- B. Risk Assessment Methods Research and Development: 5. Conduct Statistical Analyses and Modeling.
- C. Risk Assessment Data Bases and Computer Tools: 1. Technical Support
- D. Analysis, Document, and Issue Paper Preparation

PERIOD OF PERFORMANCE: CO award to 10/31/14

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the form of compiling and analyzing data on ecosystem monitoring and observing networks and to summarize the assessment of monitoring and observing network capabilities. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

This WA builds on previous EPA work that developed a survey for federal managers of monitoring and observing networks related to terrestrial and aquatic ecosystems. This WA deploys the online survey, collects responses, and analyzes the responses according to an analysis plan provided by EPA. The results of the survey and analyses will be used for a publication written in coordination with the U.S. Global Change Research Program's (USGCRP) Biodiversity and Ecosystems Cluster. The analyses of existing monitoring and observing systems will complement the USGCRP's efforts to develop a system of indicators of climate change as part of the National Climate Assessment.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows

assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas required to complete this WA.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3. Deploy survey and collect results

The Contractor shall post the existing survey files so that federal participants can access and fill out the online survey within 5 days of WA approval. Survey entries shall be collected in a suitable database for analysis. The survey shall remain open for a minimum of 8 weeks.

Task 4. Analyze results

The Contractor shall review the analysis plan provided by the WAM and suggest any changes. The Contractor shall analyze the respondents' entries, due 6 weeks after the survey closes. The contractor then shall schedule a call or meeting with the EPA WAM, appropriate EPA staff, and interested USGCRP group members to discuss draft analysis results within 2 weeks of sending draft results. After receiving comments from the WAM on draft results, the Contractor shall implement revisions and any additional analyses, due within 3 weeks. Final results are due 2 weeks after receiving comments from the WAM.

Task 5. Draft journal article and review responses

The contractor shall summarize results of the database analysis, particularly with respect to detecting impacts related to climate changes. This document shall be in a form suitable for publication in a journal such as Ecology Letters or BioScience. A draft of the document is due to the WAM 2 weeks after completing Task 4. The WAM will circulate the draft within the USGCRP group for comments. A final document is due 2 weeks after receiving comments from the WAM and USGCRP group members.

The Contractor shall assist the WAM in addressing comments generated during internal EPA and external journal reviews. Revised article and comment-response document are due 3 weeks after receiving comments from WAM.

Task 6. Communication and website materials

The Contractor shall create a presentation (compatible with PowerPoint) describing the database, survey, analyses, and results. This presentation shall be used to report back to survey participants, as well as other interested groups, such as the Department of Interior's Landscape Conservation Cooperatives and the U.S. Geological Survey's Climate Science Centers. The Contractor shall schedule a webinar for survey participants and another webinar for other interested groups. The National Climate Assessment's Indicators Working Group

members also shall be invited to participate. Presentation shall be developed and webinar scheduled within 2 weeks of sending the article for internal EPA review.

The Contractor shall develop web pages for a web portal that allows users to access the database of networks and survey information collected. It is likely that this web portal and associated explanatory pages will be hosted by either the USGCRP or the Office of Science and Technology. The WAM will provide the Contractor with contact information for the webmaster where the web portal will be housed. The Contractor shall follow the web guidelines of the hosting institution. The Contractor shall submit draft web pages to be reviewed by USGCRP group members and webmaster of the hosting institution 2 weeks after completing Task 4. Final web pages are due 3 weeks after receiving comments from WAM.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. QAPP	15 days after award
Task 3. Deploy survey and collect results	Within 5 days of WA approval
Task 4. Analyze results	Draft analysis due 6 weeks after completing Task 3
	Revised results due 3 weeks after call/meeting
	Final results 2 weeks after receiving comments from WAM
Task 5. Draft article and responses	Draft article 2 weeks after completing Task 4
	Internal review draft 2 weeks after receiving comments from
	WAM
	External review draft 3 weeks after receiving comments from
	WAM
	Final draft to journal 3 weeks after receiving comments from
	WAM
Task 6. Communication and web materials	Presentation and webinar 2 weeks after internal review begins
	(Task 5)
	Draft web pages for web portal 2 weeks after completing Task
	4
	Final web pages 3 weeks after receiving comments from WAM

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Task Order Manager (WAM)	Alternate Task Order Manager (AWAM)

Name: Britta Bierwagen Name: Susan Julius

Office: ORD/NCEA/GCRP
Office: ORD/NCEA/GCRP

1200 Pennsylvania Ave., NW (MC 8601P) 1200 Pennsylvania Ave., NW (MC 8601P)

Washington, DC 20460 Washington, DC 20460

Phone: 703-347-8613 Phone: 703-347-8619 Fax: 703-347-8694

Email: <u>Bierwagen.Britta@epa.gov</u> Email: <u>Julius.Susan@epa.gov</u>

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

INTEGRITY: 'Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.)	Bibliographic	identificati	ion of the	study.
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Study Identifiers:

Author(s):

Title:

Study Citation:

Storage location (e.g., library, facility archive, personal archive):

- 2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
- 3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
- 4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
- 5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
- 6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-10

TITLE: Preparing Materials on Public and Commercial Buildings for Pb Rulemaking

Specify Section & Paragraph SOW: D. Analysis, Document & Issue Paper Preparation

PERIOD of PERFORMANCE: 11/14/13 - 10/31/14

I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Office of Pollution Prevention and Toxics (OPPT).

II. BACKGROUND

EPA is undertaking rulemakings intended to revise certain provisions of the Lead Renovation Repair and Painting (LRRP) Rule and to cover public and commercial buildings not covered by the LRRP rule. Among the first activities was the publication of an Advance Notice of Proposed Rulemaking (ANPR) in April, 2010, for exterior renovations and interior renovations in public and commercial buildings that contain lead paint. In this ANPR, EPA had an opportunity to seek information from the public that could be used in future rulemaking. That information is now available.

EPA previously identified several analytical issues for this initial proposed rulemaking, including:

- Support for prior rulemaking estimated exposure extent by vintage of the structure. We are not aware of any statistical data on the likelihood of lead paint of any vintage on the interior or the exterior of public and commercial buildings.
- Prior rulemaking distinguished target buildings based on the year, 1978, when lead paint for residences stopped production. We do not know the extent to which lead paint was used in or on public or commercial buildings after 1978, or the lead levels in the paint.
- Support for prior rulemaking utilized information available on typical home renovations and house cleaning practices to permit comparisons for benefits calculations. We do not know what baseline practices are for renovations in public or commercial buildings, or for routine cleaning.
- It is unclear whether existing data can be used to model residential exposures to children from renovations of nearby public and commercial buildings. We do not know the extent to which dust will drift from exterior renovations onto neighboring properties (would this, for instance, resemble modeling plumes from smelters?). We also do not know how often residential properties are adjacent to public or commercial buildings, or a distribution of distances of residences from public or commercial buildings.

Under a previous work assignment, the contractor developed a draft approach for estimating the residential dust

hazard standards that would achieve each of four alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative.

On July 6-7, 2010, EPA met with a special group that was formed under the auspices of the EPA SAB so that EPA could receive expert advice on analytical issues. The final report on this consultation is available at: http://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/F8DA254881FEC6898525778F004C789A/\$File/EPA-SAB-10-011-unsigned.pdf

After EPA's July, 2010, meeting with the SAB group, the contractor carried out revisions and additional calculations under the previous work assignment to complete plans for the final approach for estimating the residential dust hazard standards that would achieve each of the three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change associated with each alternative. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers.

Under a previous work assignment, the contractor developed a draft approach for estimating the dust hazard standards for interior renovations in public and commercial buildings that would achieve each of three alternative targets for blood lead concentration in children under age 6, and for estimating the IQ change in children under age 6 associated with each alternative dust hazard standard. The contractor developed an approach for estimating certain cardiovascular effects in adults for each alternative dust hazard standard.

After EPA's July, 2010, meeting with the SAB group, the contractor carried out revisions and additional calculations under the previous work assignment to complete plans for the final approach for estimating the dust hazard standards for interior renovations in public and commercial buildings that would achieve each of the three alternative targets for blood lead concentration in children under age 6, for estimating the IQ change associated with each alternative dust hazard standard, and for estimating the cardiovascular effects in adults for each of the five alternative dust hazard standards. The contractor estimated blood lead concentrations in children under age 6 using methods based on specific epidemiology papers. For adults, based on appropriate literature, the contractor developed a method to scale from residential results for children.

The SAB Panel met again on December 6-7, 2010, and provided further draft comments to OPPT. The SAB issued the final report on this review on July 7, 2011. The final report on this review is available at: http://yosemite.epa.gov/sab/SABPRODUCT.NSF/81e39f4c09954fcb85256ead006be86e/CD05EA314294B683 852578C60060FB08/\$File/EPA-SAB-11-008-unsigned-revised.pdf

Rulemaking will require economic analysis, including benefits analysis. Benefits analysis for the rulemaking will require modeling of Intelligence Quotient (IQ) change in children under age 6.

Under a previous work assignment, the contractor supported the development of a benefits analysis for a proposed rule for exterior renovations on public and commercial buildings that contain lead paint. The contractor met several times with the Work Assignment Manager (WAM), other EPA staff, and the economics contractor via teleconference to discuss the requirements of the benefits analysis for the rulemaking on exterior renovations on public and commercial buildings that contain lead paint. The contractor sketched frameworks for these analyses and identified desirable data to support them. The contractor developed an approach for providing support to the benefits analysis. The contractor developed a model to estimate IQ changes in children under age 6 as a result of their exposure to lead from exterior renovations at public and commercial buildings.

The contractor conducted the analyses that provide support to the benefits analysis. The contractor estimated the IQ changes for use by the economics contractor in the benefits analysis.

Under a previous work assignment, the contractor responded to a series of technical directions and work assignment amendments designed to encompass support to rulemaking on exterior renovations at public and commercial buildings. The technical directions and amendments included: updated meteorology information for AERMOD modeling, addition of exposure pathway of air infiltration and track-in back into the same public and commercial buildings, addition of various public and commercial buildings as receptor buildings, addition of modeling exposure and blood lead modeling for adults, additional considerations for Leggett and IEUBK blood lead modeling, and sensitivity analyses.

Under a previous work assignment, the contractor received data received after a Federal Partners meeting held in August of 2013. This data was analyzed and incorporated into the exteriors or interiors analysis as appropriate.

Under a previous work assignment, the contractor supported the development of a benefits analysis for a proposed rule for interior renovations on public and commercial buildings that contain lead paint. The contractor met several times with the Work Assignment Manager (WAM), other EPA staff, and the economics contractor via teleconference to discuss the requirements of the benefits analysis for the rulemaking on interior renovations within public and commercial buildings that contain lead paint. The contractor sketched frameworks for these analyses and identified desirable data to support them. The contractor developed an approach for providing support to the benefits analysis. The contractor developed a model to estimate IQ changes in children under age 6 and blood lead changes in adults as a result of their exposure to lead from interior renovations at public and commercial buildings. The contractor, in coordination with EPA staff, developed a framework to initiate Monte Carlo modeling including identification of desired scenario and sampled variables and associated data sources.

This work assignment will consist of a series of technical directions designed to encompass support to rulemaking on interior and exterior renovations at public and commercial buildings.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. This work assignment will require contractor staff to be thoroughly familiar with the IQ change analysis that was performed for the 2008 LRRP final rule. That rule and directions to its support materials may be found at

http://www.epa.gov/lead/pubs/renovation.htm. Contractor staff with expertise in pharmacokinetic modeling of lead, biostatistics for lead, and computer modeling for lead are essential for this work assignment.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)"; and "Appendix A. Guidance on Quality Assurance Project Plans for Secondary Research Data."

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved. The contractor shall not perform any computer modeling work under this work assignment until the quality assurance statement is reviewed and approved by the WAM and the OPPT QA Manager.

Task 3: Hazard Finding Approach

The contractor shall support the development of a revised hazard finding approach under section 403 of the Toxic Substances Control Act for public and commercial buildings and residences that contain lead paint. In July, 2011, the SAB issued its final report. The WAM will issue technical direction to the contractor for any necessary updates to the final approach, its descriptive document, and the estimates associated with candidate hazard standards. The deliverable for this task will be a separate report which will document a risk-based approach to making the hazard finding.

Task 4: Updated Exteriors Analysis

The contractor shall support the development of a benefits analysis for a proposed rule for interior and exterior renovations of public and commercial buildings that contain lead paint. Task 4 is specific to the exteriors portion of the analysis. The contractor shall update the report based on results of revised modeling completed under the previous work assignment. Discussion of proximity or distance, renovation activities, and appropriate matching of exterior and interior building configurations and associated IQ and blood lead changes will be expected.

Task 5: Interiors Analysis and Consolidated Report for Interiors and Exteriors

The contractor shall support the development of a benefits analysis for a proposed rule for interior and exterior renovations on public and commercial buildings that contain lead paint. Task 3 is specific to the interiors portion of the analysis. The contractor shall meet regularly with the WAM, other EPA staff, and the economics contractor via teleconference or in person to discuss the requirements of the benefits analysis for rulemaking on interior and exterior renovations in public and commercial buildings that contain lead paint. The contractor shall summarize the meetings and sketch frameworks for these analyses and identify desirable data to support them. The WAM will issue technical direction to the contractor for any necessary blood lead modeling, and modeling of IQ change in children under age 6, for inclusion in the benefits analysis. The contractor shall estimate loadings based on dust study experiment maps and associated supporting information from other relevant data sources, such as the Environmental Field Sampling Survey (EFSS) study conducted by OPPT, or

data received from Federal partners from a request in Fall of 2013. The contractor shall develop an approach for providing support to the benefits analysis. The contractor shall conduct the analyses that provide support to the benefits analysis. The deliverable for Tasks 4 and 5 will be a consolidated report that summarizes modeling results, trends, and approaches for both exteriors and interiors. Appendices can be used as appropriate to describe supporting information as long as they are referenced appropriately in the main document.

IV. SCHEDULE OF DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award

By January 31, 2014, the contractor shall deliver to the WAM a final report for Task 3, as prescribed by the WAM.

By February 1, 2014, the contractor shall deliver to the WAM a final report for Task 4, as prescribed by the WAM.

By April 1, 2014, the contractor shall deliver to the WAM a draft report for Task 5, including the analyses that provide support to the benefits analysis, in a format to be specified based on the needs of the economics contractor which will be specified via written technical direction from the WAM.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM, or CO.

VI. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)

Charles Bevington

1200 Pennsylvania Avenue, NW (7406M)

Washington, DC 20460 Telephone: 202-564-8814 Fax: 202-564-8892

Alternate Work Assignment Manager

Amuel Kennedy

1200 Pennsylvania Avenue, NW (7403M)

Washington, DC 20460 Telephone: 202-564-7609 Fax: 202-564-1626

Physical Address:

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

EPA East, room 5102L

Washington, DC 20004

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Other Agency Official Name Adam Meier								Branch/Mail Code:			
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Contracting Official Name Matthew Growney						Branch/Mail Code:					
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SFO (Max 2)							
_Φ DCN Budget/FY App	ropriation Budget Org/Code	Program Element Object Class	Amount (Dollars) (Cents) S	Site/Project Cost Org/Code			
<u></u>	le (Max 6) (Max 7)	(Max 9) (Max 4)	Amount (Bollars) (Gents)	(Max 8) (Max 7)			
1							
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3			,				
4							
5			·				
	Autho	rized Work Assignment Ceili	g				
Contract Period: 11/01/2013 To 10/31/201	Cost/Fee: \$224,535.00)	LOE: 2267				
This Action:	\$50,360.00		505				
	430,300.00		303	_			
Total:	\$274,895.00		2,772				
	Work	Plan / Cost Estimate Approv	ıls				
Contractor WP Dated: 07/09/201	4 Cost/Fee: \$5(0,360.00	LOE: 505				
Cumulative Approved:	Cost/Fee: \$2	74,895.00	LOE: 2,772				
Work Assignment Manager Name Char	les Bevington		Branch/Mail Code:				
			Phone Number 202-564-8814				
(Signature)		FAX Number:					
Project Officer Name Melissa Rev	ely-Wilson	Branch/Mail Code:					
		Phone Number: 703-347-8523					
(Signature)		FAX Number: 703-347-8696					
Other Agency Official Name		Branch/Mail Code:					
			Phone Number:				
(Signature)		(Date)	FAX Number:				
Contracting Official Name Matthew	Growney	Branch/Mail Code:					
1		Phone Number: 513-487-2029					